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ORGAN TRANSPLANTS

Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs



Human Resources Division

B-246768

April 22, 1993

The Honorable Edward M. Kennedy, Chairman,
The Honorable Nancy L. Kassebaum,
Ranking Minority Member,
Committee on Labor and Human Resources
United States Senate

The Honorable John D. Dingell, Chairman,
The Honorable Carlos J. Moorhead,
Ranking Minority Member,
Committee on Energy and Commerce
House of Representatives

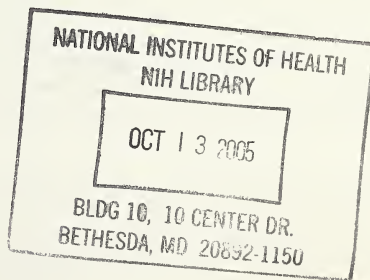
This report responds to a provision of the Transplant Amendments Act of 1990 (P.L. 101-616) that required us to study the effectiveness of the organ procurement and allocation system. We include recommendations to the Secretary of Health and Human Services that could better ensure the equitable allocation of organs and increase the effectiveness of organ procurement activities.

We are sending copies of the report to the Secretary of Health and Human Services, the Director of the Office of Management and Budget, and other interested committees and parties. We also will make copies available to others on request.

Please call me on (202) 512-7119 if you or your staff have any questions about this report. Other major contributors are listed in appendix 12.



Mark V. Nadel
Associate Director, National and
Public Health Issues



Executive Summary

Purpose

Over a recent 5-year period, over 10,000 people died waiting for an organ transplant. Although the technology for transplanting organs has improved dramatically, the gap between transplant demand and organ supply has widened. From 1988 to 1992, the annual number of people waiting for transplants rose by 66 percent, whereas the number of organ donors grew by only 13 percent. In 1992 there were 4,497 organ donors.

With the passage in 1984 of the National Organ Transplant Act, the Congress sought to increase the supply of transplant organs—such as kidneys and hearts—and improve the equity of their allocation by establishing a national network for organ procurement and allocation. In 1990 the Transplant Amendments Act mandated that GAO study the effectiveness of the organ procurement and allocation system. In this report, GAO addresses whether (1) organs are being equitably distributed, (2) organ procurement organizations (OPOs) are obtaining an adequate number of potential donors, and (3) the Department of Health and Human Services (HHS) is adequately monitoring these organizations' organ procurement and allocation efforts.

Background

In 1986 HHS awarded the contract to establish the national procurement and allocation network to the United Network for Organ Sharing (UNOS). The contract requires UNOS to maintain a national computerized list of patients awaiting an organ transplant, set criteria for allocating organs to these patients, and help organ procurement organizations make the allocations. HHS is responsible for designating organ procurement organizations, which serve specified geographic areas. The Division of Organ Transplantation within the Health Resources and Services Administration (HRSA) coordinates federal organ transplant policy. The Health Care Financing Administration (HCFA) sets various standards relevant to Medicare and Medicaid participation. As of July 1992, the national organ transplantation system consisted of the network contractor UNOS, 67 organ procurement organizations, and about 250 hospitals performing organ transplants.

In fulfillment of the network contract, UNOS developed allocation criteria for determining which patients would be selected to receive organs. The criteria are based on medical concerns for transplant effectiveness and patient concerns for fairness. Specifically, the National Organ Transplant Act requires organ procurement organizations to distribute organs equitably among patients on the basis of medical criteria. The criteria are

weighted to rank patients according to such factors as medical urgency, length of time waiting for an organ, and organ compatibility.

To conduct its study, GAO (1) surveyed the allocation and procurement policies of the 68 organ procurement organizations, (2) interviewed officials and reviewed records at 10 organ procurement organizations, and (3) interviewed officials of HHS and the Joint Commission on Accreditation of Healthcare Organizations, transplant surgeons, and others involved in the field of organ transplantation.¹

Results in Brief

Despite federal legislation to increase the acquisition and standardize the distribution of transplant organs, patients cannot be assured that organ procurement organizations are making equitable allocation decisions based on medical criteria or effectively boosting the organ supply due to several factors.

First, HHS cannot assure that organs are allocated equitably because it does not monitor and assess OPO allocation practices. Second, some organizations limit the pool of patients to be considered for transplant to a single transplant center. This practice is inconsistent with federal requirements unless based on medical criteria and may exclude from consideration higher ranked patients from other transplant centers. Third, some organizations do not document why patients who were well suited to receive an organ were skipped over. Therefore, these organizations are not able to demonstrate that their organ distribution decisions are made equitably. Finally, despite efforts by UNOS to make allocation practices uniform, organ procurement organizations' adherence to UNOS policies is voluntary because the policies are nonbinding.

In addition, HHS has not adequately monitored or evaluated the success of organ procurement organizations' efforts to obtain organ donors. Without assessing performance, HHS cannot target assistance to organ procurement organizations that fall short of their potential to obtain donors.

To assure that patients are selected equitably and that the greatest number of available organs are obtained, HHS should develop federal regulations stipulating appropriate allocation practices and develop a measure of procurement success that would enable the Department to target technical assistance to less effective organ procurement organizations.

¹At the time GAO surveyed the organ procurement organizations, there were 68; as of July 1992, however, the number of organizations decreased to 67 after the merger of two service areas into one.

Principal Findings

HHS Does Not Assess Impact of Changes to UNOS Allocation Criteria

There are differences of opinion among transplant surgeons and others as to the weight specific medical criteria should be given when ranking potential recipients. In GAO's survey of organ procurement organizations, 25 reported altering the priority weights assigned to the UNOS criteria for ranking patients. For example, some organizations increased the weight given to those patients waiting the longest for organs or to those whose conditions are most urgent. However, neither HHS, UNOS, nor the organ procurement organizations evaluate these changes to determine their impact on the equitable distribution of organs nor the merit of incorporating these changes into UNOS allocation criteria.

Despite UNOS policy that organ procurement organizations should obtain UNOS approval for modifying patient ranking criteria, until recently UNOS did not have specific guidelines for granting approval. Some of the organ procurement organizations did not obtain UNOS approval before altering the criteria.

Failure to Use Areawide List Denies Organs to Higher Ranked Patients

In selecting organ recipients, some organ procurement organizations use individual transplant center lists, consisting of patients from a given transplant center, rather than the areawide list of the organ procurement organization, consisting of patients from all transplant centers in the organization's service area. As a result of this practice, higher ranked patients at other transplant centers in the service area can miss their chance of getting a transplant, a result that, unless it can be shown to have been based on medical criteria, would violate the National Organ Transplant Act.

Inadequate Documentation Raises Questions on Equity of Allocations

UNOS policy stipulates that organ procurement organizations document their patient selection decisions. Such documentation can demonstrate an organization's adherence to criteria for selecting organ recipients. At 10 organ procurement organizations, GAO found that the level of documentation of allocation decisions varied considerably. In the absence of adequate documentation, organ procurement organizations cannot demonstrate that their patient selection decisions have been made equitably.

UNOS Policies to Make Selection Practices Consistent Not Binding

In November 1992, UNOS adopted policies calling for organ procurement organizations to (1) use a single patient recipient list that encompasses an organization's entire service area, (2) submit justifications for deviating from UNOS allocation criteria, and (3) provide UNOS with assessment data on the impact of modified allocation criteria. However, the policies of UNOS, a private contractor, are advisory. HHS must develop these policies as federal regulations for them to become requirements with which organ procurement organizations and transplant centers must comply.

Success of Organ Procurement Organizations' Efforts to Increase Organ Supply Unknown

HRSA and the Network contractor, UNOS, are responsible for overseeing the effectiveness of the organ procurement organizations in increasing the organ supply. Neither, however, has monitored the organizations' procurement efforts or adopted a measure for assessing procurement effectiveness. Donor procurement rates—consisting of the number of donors procured per million population within a geographic service area—varied among the 68 organ procurement organizations GAO surveyed. Because this ratio does not include the number of potential organ donors, the procurement rate is not an adequate measure of procurement success. HHS has not developed a meaningful measure or used available measures to assess effectiveness.

Targeted Technical Assistance Needed to Increase Organ Procurement

Neither UNOS nor HRSA systematically targets technical assistance to organ procurement organizations that may need help obtaining donors. In the absence of an effective measure of procurement performance, the agencies cannot identify which organ procurement organizations would benefit the most from technical assistance. However, UNOS and HRSA have taken some outreach actions, including efforts to educate the general public about the need for donations and efforts to improve the solicitation of organ donations at hospitals.

Recommendations

To better ensure that the national organ procurement and allocation system allocates organs equitably and obtains the greatest number of available organs, GAO is making several recommendations to HHS regarding the allocation and procurement practices of organ procurement organizations. These include requiring organ procurement organizations and transplant centers to

- use Network criteria for selecting patients to receive organs or to use an approved change to those criteria,

- use a single OPO-wide list when allocating organs unless a center-specific allocation is justified for medical reasons, and
- document their allocation decisions.

In addition, GAO recommends that HHS (1) evaluate the outcome of modifications made to established patient selection criteria and (2) establish criteria for determining the success of organ procurement organizations in increasing the supply of transplant organs and target technical assistance to organ procurement organizations identified as least effective.

Agency Comments

GAO met with officials from HCFA, HRS, and UNOS and with HHS's Office of the Assistant Secretary for Planning and Evaluation and discussed a draft of this report. Based on these discussions, GAO incorporated their comments where appropriate.

Contents

Executive Summary		2
Chapter 1		12
Introduction	National Organ Transplantation Policy	14
	Organ Procurement and Transplantation Network Established	16
	How Organs Are Procured and Allocated for Transplantation	17
	Objectives, Scope, and Methodology	19
Chapter 2		21
Process to Allocate	HHS and UNOS Have Not Determined If OPO Variances to UNOS	21
Organs to Waiting	Allocation Criteria Benefit Patients	
Patients May Raise	Higher Ranked Patients Not Always Considered by Some OPOs	25
Questions About	Inadequate Documentation May Raise Questions About OPO	28
Equity	Allocation Practices	
	HHS Action Hinders UNOS' Ability to Ensure Adherence to	29
	Allocation Policies	
Chapter 3		31
OPOs Not Assessed	Different OPO Practices Could Account for Procurement Rate	31
on Ability to Obtain	Differences	
Available Organs	Most OPOs Collect Data on Their Organ Procurement Process	34
	HHS Not Adequately Assessing OPO Procurement Efforts and	38
	Effectiveness	
	Technical Assistance Not Targeted to Problem OPOs	40
Chapter 4		43
Conclusions and	Conclusions	43
Recommendations	Recommendations	44
Appendixes		
	Appendix I: UNOS Criteria for Ranking Patients Waiting for	46
	Organ Transplants	
	Appendix II: HHS Letter Stating Their Position on OPOs' Use of	49
	Transplant Center-Specific Lists	
	Appendix III: Variations in OPO Kidney Allocation	51
	Appendix IV: Reasons for Not Selecting Potential Recipients	54
	Under Consideration (Based on 419 Organ Placements)	
	Appendix V: Variations in OPO Procurement in 1991	55
	Appendix VI: Status of Required Request and Routine Inquiry	58
	Laws	

Appendix VII: Alternatives for Meeting the Demand for Organ Transplantation	61
Appendix VIII: HHS Letter Stating Their Position on Arrangements Between Hospitals and OPOs	66
Appendix IX: Data Supporting Figures in Report	68
Appendix X: U.S. General Accounting Office Survey of Organ Procurement Organizations' Procurement and Allocation Practices	69
Appendix XI: Rationale for Presenting Questionnaire Data	87
Appendix XII: Major Contributors to This Report	91

Bibliography	92
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Tables	
Table 2.1: Variances to UNOS Criteria for Ranking Kidney Patients	22
Table 2.2: Variances to UNOS Criteria for Ranking Heart Patients	23
Table 2.3: Variances to UNOS Criteria for Ranking Liver Patients	23
Table 3.1: Information Collected by OPOs on Potential Organ Donors Referred During 1991	37
Table 3.2: UNOS Activities to Promote Organ Donation.	41
Table 3.3: HRSA Activities Intended to Increase Organ Donation	42
Table VI.1: OPOs' Opinions on the Effectiveness of the Federal Routine Inquiry Law on Organ Procurement Activities	59
Table IX.1: Data for Figure 1.1	68
Table IX.2: Data for Figure 3.1	68
Table XI.1: Modifications to UNOS Criteria for Prioritizing Potential Kidney Recipients	87
Table XI.2: Modifications to UNOS Criteria for Prioritizing Potential Heart Recipients	87
Table XI.3: Modifications to UNOS Criteria for Prioritizing Potential Liver Recipients	88
Table XI.4: GAO Criteria for Classifying OPOs' Kidney Allocation Systems	89
Table XI.5: GAO Criteria for Classifying OPOs' Heart Allocation Systems	89
Table XI.6: GAO Criteria for Classifying OPOs' Liver Allocation Systems	90
Table 3.3: HRSA Activities Intended to Increase Organ Donation	95

Figures

Figure 1.1: Demand for Organs and the Number of Organs Donated	13
Figure 1.2: Many Entities Play a Role in Organ Transplantation	15
Figure 3.1: Reduction of the Donor Pool During the Organ Donation Process	36

Abbreviations

GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
HLA	human leukocyte-associated antigens
OPO	organ procurement organization
OPTN	Organ Procurement and Transplantation Network
UNOS	United Network for Organ Sharing

Introduction

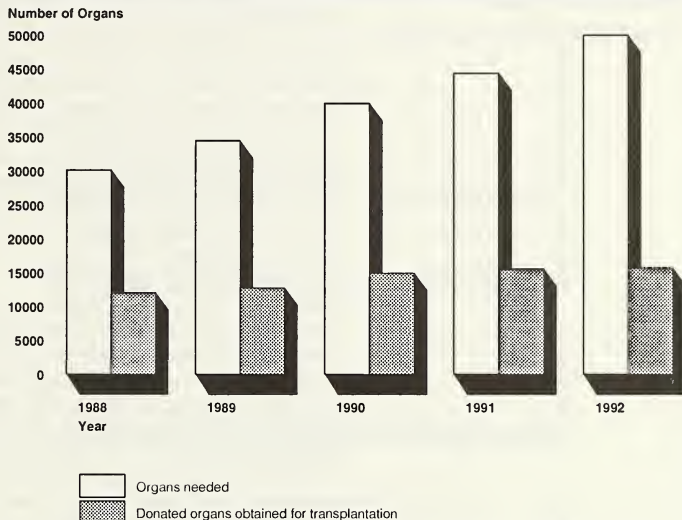
Organ transplant technology has improved dramatically in recent years and organ transplantation is now an accepted and effective means of treating a significant number of patients with life-threatening organ failure. Consequently, the number of transplants each year has been increasing, with over 16,000 transplants performed in 1991. While transplantation is not without potential drawbacks, survival rates have increased, with some patients returning to productive lives.¹

A serious problem limiting organ transplantation is the increasing gap between the demand for and supply of organs. As shown in figure 1.1, between 1988 and 1992, the annual number of people waiting for organs has increased by 66 percent, reaching a total of 49,933 in 1992. During the same time period, the annual number of organs increased by only 31 percent, with 4,497 donors² providing 15,715 organs in 1992. During these 5 years, over 10,000 people died waiting for an organ transplant.

¹Immunosuppressive drug therapy, which is used to keep the recipient's immune system from rejecting a transplanted organ, has side-effects that may include hypertension, gastrointestinal symptoms, kidney dysfunction, and infection. New treatment approaches with less toxicity are being tested.

²Throughout this report, unless otherwise noted, donor is defined as a deceased patient from whom one or more organs are removed for the purpose of transplantation.

Figure 1.1: Demand for Organs and the Number of Organs Donated (1988 to 1992)



Notes: During 1992, 49,933 patients were listed on the UNOS waiting list. As of December 31, 1992, there were 29,519 patients on the UNOS waiting list. UNOS characterized the 12,006 donated organs for transplant in 1992 as a preliminary figure.

UNOS provided the total number of patients on the UNOS waiting list by year to approximate the number of organs needed in each year. These figures do not include patients not registered with UNOS.

Source: UNOS.

With this growing organ shortage, the Congress has taken actions to encourage increased organ donation and ensure that organs are allocated fairly by establishing national organ transplantation policy. The Transplant Amendments Act of 1990 mandated that GAO conduct a study evaluating organ procurement efforts and the equitable allocation of organs.

National Organ Transplantation Policy

In 1984, the National Organ Transplant Act (P.L. 98-507) amended the Public Health Service Act to establish a national organ transplantation policy. Additional amendments were passed in 1988 (P.L. 100-607) and in 1990 (P.L. 101-616). The law (1) directed the Secretary of Health and Human Services (HHS) to contract for the establishment of the Organ Procurement and Transplantation Network or OPTN,³ (2) directed the Secretary of HHS to establish the Task Force on Organ Transplantation to study and make recommendations to improve the field of transplantation, (3) directed organ procurement organizations (OPOs) participating in the Network to distribute donated organs equitably among transplant patients and to work to increase the supply of donated organs, and (4) prohibited the sale of organs.

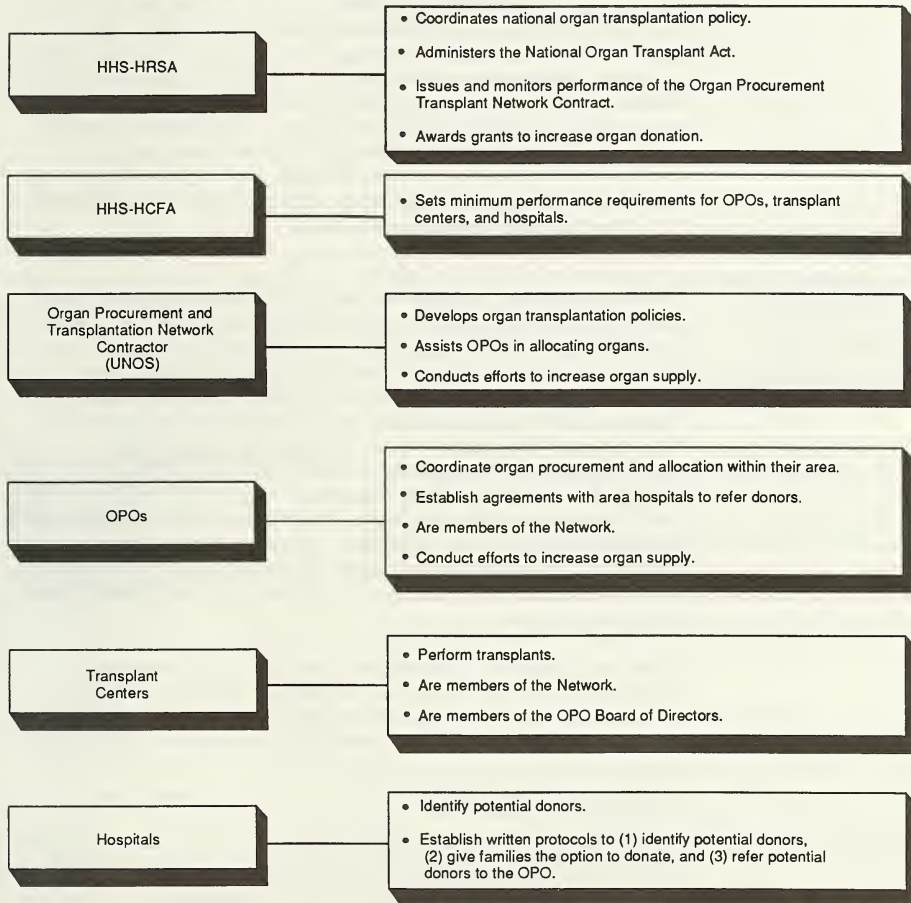
Two administrative units within HHS have specific responsibility for developing organ transplantation policy—the Health Resources and Services Administration (HRSA) and the Health Care Financing Administration (HCFA). Designated as the unit to administer the National Organ Transplant Act, HRSA is responsible for (1) ensuring that statutory requirements are met, (2) informing the public of the need for organ donations, (3) providing technical assistance to OPOs, and (4) informing patients, their families, and physicians about transplantation policies and resources. In addition, HRSA also funds specific organ procurement and allocation activities through the Network, the scientific registry, and grants for increasing organ donation.^{4, 5} (Fig. 1.2 identifies the roles of federal agencies, the Network, transplant centers, and hospitals.)

³For ease of discussion OPTN will be referred to as the Network.

⁴The contract for the scientific registry requires UNOS to collect sociodemographic and medical data on all transplant recipients and to track their postoperative progress.

⁵In fiscal year 1991, according to UNOS officials, HRSA spent approximately \$1.4 million for operation of the Network, \$1.1 million for operation of the scientific registry, and \$300,000 for grants.

Figure 1.2: Many Entities Play a Role in Organ Transplantation



HCFA is responsible for administering section 1138 of the Social Security Act (42 U.S.C. 1320b-8), which was added by the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509). Section 1138 required (1) all hospitals participating in Medicare and Medicaid to establish written protocols for identifying potential organ donors and assuring that families are aware of the option to donate organs or to decline donation; (2) the Secretary of HHS to designate one OPO per service area; (3) OPOs to meet standards and qualifications in order to receive payment from Medicare and Medicaid; and (4) OPOs and transplant centers participating in Medicare and Medicaid to be members of the Network, abide by its rules and requirements, and to allocate organs in accordance with established medical criteria and Network requirements.

Organ Procurement and Transplantation Network Established

In 1986, HHS awarded a contract to the United Network for Organ Sharing (UNOS) to operate the Organ Procurement and Transplantation Network. As of July 1992, the Network's members included 67 HHS-designated OPOs and over 250 transplant centers throughout the United States.⁶ Also included as voluntary members of UNOS are tissue typing laboratories, voluntary health organizations, and members of the general public. Both federal law and the contract require the Network to assist OPOs in allocating organs and to maintain a national computerized list of individuals waiting for an organ transplant.⁷ ⁸ To develop the list, potential recipients are registered with UNOS and their medical profiles entered and stored in a UNOS computer. In addition, the federal law and contract require the Network to develop policies governing membership criteria and to set medical criteria and quality standards for the procurement and allocation of organs.

While UNOS's board of directors⁹ has developed policies governing membership and procurement and allocation of organs, these policies currently are considered voluntary guidance to OPOs and other Network members. HCFA, reluctant to have UNOS—a private sector entity—establish

⁶Throughout this report, reference will be made to the 68 OPOs that were designated as of December 1991, when we surveyed them.

⁷Only those patients who are accepted by a transplant program are registered with UNOS. A transplant center may have medical and financial criteria that patients must meet. For example, most heart transplant patients must be under a certain age, emotionally stable, free from any conditions that preclude transplantation, and able to pay for the transplant. See Heart Transplants: Concerns About Cost, Access, and Availability of Donor Organs (GAO/HRD-89-61, May 3, 1989).

⁸UNOS permits more than one transplant center to list the same patient with UNOS.

⁹The National Organ Transplant Act requires the board of directors to include representatives of OPOs, transplant centers, voluntary health associations, and the general public.

binding rules and requirements, published notice in December 1989 that no rule, requirement, policy, or other issuance of the Network was to be considered a binding “rule or requirement” unless approved by the Secretary of HHS.¹⁰ Furthermore, the notice indicated that no entities could be considered out of compliance with Network membership requirements except as permitted by the Secretary.¹¹ Since that time, HRSA has been in the process of developing regulations for approval by the Secretary of HHS. Although compliance with UNOS rules is voluntary, HRSA and UNOS officials believe OPO compliance with UNOS rules is high.

OPOS play an essential role in organ transplantation by coordinating organ procurement and allocation. Funded primarily through Medicare reimbursements administered by HCFA, OPOS allocate organs according to national policies and their own. To increase the organ supply, OPOS provide professional and public education to encourage donation and work with hospitals to recover organs from donors. While they have similar responsibilities, the OPOS vary widely in the geographic size and demographic composition of their service area,¹² as well as in the number of hospitals, transplant centers, and patients served.

How Organs Are Procured and Allocated for Transplantation

Organ donation is dependent on voluntarism and generosity as well as solicitation and decisionmaking at a time when family members are under the stress of bereavement. Typically this process begins at a hospital when a patient is identified as a potential organ donor. Only those patients pronounced brain dead are considered for organ donation.¹³ Patients who become organ donors tend to be males between the ages of 19 and 49 who have died from some type of head trauma resulting from nonaccidental injury, such as a brain hemorrhage, or an accidental injury, such as a motor vehicle accident.

Once a potential organ donor has been identified, the patient's family is contacted by a staff member of either the hospital or the OPO and the family is given the opportunity to donate the deceased's organs. If the

¹⁰See Harold J. Krent, “Fragmenting the Unitary Executive: Congressional Delegations of Administrative Authority Outside the Federal Government,” *Northwestern University Law Review*, Vol. 85 (1990), p. 62 and p. 96, note 108, for a brief discussion of the statutory arrangement at issue.

¹¹In 1988, the law was amended to expressly direct the Network to establish membership and medical criteria for allocating organs and provide members of the public an opportunity to comment with respect to such criteria.

¹²HHS is required to designate one OPO per service area. A service area must be of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs.

¹³States set the legal standard for determining death. Brain death is defined as the irreversible cessation of all functions of the entire brain, including the brain stem.

family consents to donation, OPO staff coordinate the remainder of the organ procurement activities, including recovering and preserving the organs and arranging for their transport.

When an organ becomes available, the OPO staff typically identify the potential recipients from the UNOS computer system. The UNOS computer matches each patient in the UNOS database against the donor's characteristics and then generates a ranked list of potential recipients for that particular donor (that is, each donor entered generates a different ranked list of potential recipients).

UNOS developed criteria for selecting patients to receive an organ. Patients are ranked using several factors. For example, potential kidney recipients are prioritized according to such factors as degree of antigen match,¹⁴ blood type, length of time on the waiting list, age (for pediatric patients), and immune status.¹⁵ For the heart, heart-lung, liver, lung, and pancreas, the potential recipient's degree of medical urgency, blood type, and length of time on the waiting list are factors affecting ranking.¹⁶ Some OPOs have adjusted the UNOS allocation criteria for patients in their service area.¹⁷ UNOS's policy permits OPOs to change UNOS allocation criteria, typically after the change has been presented to and approved by UNOS.

After obtaining the list of potential recipients, the OPO staff first contacts the surgeon for the patient at the top of the list and offers the organ.¹⁸ If the organ is declined, the organ is offered to a surgeon(s) for other patients according to the order they appear on the ranked list. If the organ cannot be allocated within the OPO's service area, it is next offered to surgeons for potential recipients within the UNOS region the OPO is located in and, if

¹⁴Efforts are made to match the donor's and recipient's genetic make-up by comparing six human leukocyte-associated (HLA) antigens of the potential recipients with those of the donor.

¹⁵Highly sensitized patients have antibodies in their immune system that make them likely to reject most organs.

¹⁶As noted earlier, allocation criteria are not legally binding.

¹⁷Patients within the OPO service area are generally ranked ahead of patients outside the service area. UNOS has concluded that, with the technology currently available, it is not feasible to distribute all organs employing a single national list. See The Feasibility of Allocating Organs on the Basis of a Single National List, UNOS (Richmond, Va.: 1991).

¹⁸According to a UNOS official, OPOs allocate, that is, determine which patient will receive an organ; however, a transplant center or UNOS may also allocate organs.

necessary, it is then offered on a nationwide basis.^{19, 20} Once the recipient is selected and all testing is complete and indicates compatibility of donor and recipient, surgery is scheduled and the transplant takes place.

Objectives, Scope, and Methodology

In the Transplant Amendments Act of 1990, the Congress mandated that GAO study and report on the effectiveness of the national organ procurement and allocation system. In this report we address the following issues:

- whether the national system equitably distributes organs to patients on transplant waiting lists;
- how effective the OPOS are in procuring organs;
- the degree to which HHS is monitoring the OPOS' organ procurement and allocation efforts; and
- the effectiveness of federal and state required request laws.²¹ (See app. VI.)

In conducting this study, we reviewed relevant literature and federal legislation and regulations. We interviewed officials of HRSA's Division of Organ Transplantation, HCFA headquarters, and the 10 HCFA regions. We also interviewed officials at UNOS, six transplant centers, and the Association of Organ Procurement Organizations as well as various health policy experts. During the early stages of our study, we visited the Washington Regional Transplant Consortium and the Regional Organ Procurement Agency of Southern California where we gained much of our initial understanding of OPO operations.

Additionally, we interviewed officials of the Joint Commission on Accreditation of Healthcare Organizations,²² from which we obtained data on hospitals' compliance with HCFA requirements from its 1991 survey of hospitals.

We mailed a questionnaire (see app. X) to all 68 OPOS. We requested information on their procurement and allocation activities, as well as their

¹⁹If a potential kidney recipient's six HLA antigens appear identical to those of the donor, that recipient is first offered the kidney, regardless of location. Such matches offer the best chance of long-term graft survival, but are not very common.

²⁰UNOS has divided the country into 11 regions for allocating organs. Each region is represented on the UNOS Board of Directors and permanent standing committees. These regions are different from HCFA regions.

²¹Required request laws require hospitals to make families of potential donors aware of the opportunity to donate.

²²The Joint Commission is a private sector entity that reviews most hospitals for compliance with standards, including those similar to the federal required request law.

policies and procedures for calendar years 1989, 1990, and 1991. One-hundred percent of OPOs responded by answering all or part of our questionnaire.

In order to obtain more detailed information on OPOs' procurement and allocation activities, we also visited 10 OPOs where we conducted interviews and reviewed case files. The OPOs were chosen to obtain information on a variety of allocation practices and levels of procurement as well as to obtain some geographic representation; however, because OPOs were not randomly selected, the findings at these 10 OPOs cannot be generalized to all OPOs. Our case file reviews consisted of evaluating the allocation of all organs procured by the 10 OPOs in September, October, and November 1991 to determine (1) the extent to which patients were excluded from initial consideration for an organ, (2) the extent to which the recipient selection process was documented, and (3) donor characteristics.

The 10 OPOs we visited were:

- California Transplant Donor Network, San Francisco, California;
- Regional Organ Procurement Agency of Southern California, Los Angeles, California;
- Lifelink of Southwest Florida, Inc., Sarasota, Florida;
- University of Miami OPO, Miami, Florida;
- Louisiana Organ Procurement Agency, Metairie, Louisiana;
- New England Organ Bank, Brookline, Massachusetts;
- Lifesource, Upper Midwest OPO, Minneapolis, Minnesota;
- New York Regional Transplant Program, Inc., New York, New York;
- Pacific Northwest Transplant Bank, Portland, Oregon; and
- Sacred Heart Medical Center OPO, Spokane, Washington.

We conducted our work from December 1991 through July 1992 in accordance with generally accepted government auditing standards.

Process to Allocate Organs to Waiting Patients May Raise Questions About Equity

Despite the establishment of the Organ Procurement and Transplantation Network run by UNOS to standardize organ allocation practices, all organ procurement organizations (OPOs) do not follow the same procedure in deciding how to allocate organs among patients waiting for transplants. HHS has not assessed the impact of the differences in OPOs' patient selection process on the equity of organ allocation.

Generally, those involved in overseeing and administering organ procurement and allocation—HHS agencies, UNOS, and OPOs—agree on the criteria used for ranking waiting patients, but differ on how to weight these criteria. In some cases, OPOs modify the weights assigned to the criteria set forth by UNOS. Neither HHS, UNOS, nor the OPOs assess the impact of OPO allocation practices that depart from systemwide UNOS policies. Therefore, they are not in a position to demonstrate if these practices are equitable. Another practice used by OPOs is to give priority to patients at a particular transplant center rather than to patients at all transplant centers within the OPO service area. This practice, unless based on medical criteria, is inconsistent with federal law requiring equitable distribution of organs.

HHS and UNOS Have Not Determined If OPO Variances to UNOS Allocation Criteria Benefit Patients

Identifying the most equitable way to allocate the limited supply of organs to waiting patients is difficult. First, transplantation science and technology continues to evolve and may require that transplantation practices be changed. Second, there are differences of opinion among transplant surgeons and others as to the weight that each criterion should be given when ranking potential recipients. For example, the weight given to medical urgency is controversial. Some believe that patients who will soon die without a transplant should be given a higher rank than other patients. Others believe that giving more weight to the sickest patients may not result in the best use of scarce organs. Transplantation of an organ to the sickest patient may not be as successful as to a patient who is not as sick. For this and other reasons, OPOs and transplant centers change the UNOS allocation criteria if they believe these modifications—that is, variances—are more equitable to the patients waiting and a more effective use of the limited organ supply. (See app. I for UNOS allocation criteria.) Although UNOS requests that variances to its allocation criteria be approved by the UNOS board, UNOS has not had explicit guidelines for approving and tracking OPO variances until recently. As a result, UNOS could not identify all the different variances OPOs and transplant centers use. For variances they approved, UNOS could not, in most cases, provide documentation explaining why the UNOS board of directors approved each of the variances. A federally funded study published in August 1990

recommended that UNOS “review all relevant data . . . to determine what the impact on patients is likely to be.”¹ Despite this recommendation, we found UNOS had approved some OPO or transplant center variances without documenting the justification for the variance.

To obtain a better understanding of the variances made to UNOS criteria, we conducted a survey of OPO allocation practices. Twenty-five of the 68 OPOS had adopted at least 1 variance to the UNOS criteria for ranking patients on a waiting list. Of these 25 OPOS, 17 had variances for ranking kidney patients, 15 had variances for ranking heart patients, and 5 had variances for ranking liver patients. Eleven of these OPOS had adopted variances without UNOS approval or knowledge.

Many of the OPO variances altered the weight given for one of the factors used in ranking patients on the waiting list (see tables 2.1-2.3). Five OPOS reduced or eliminated the weight given for antigen matching in ranking potential kidney recipients in their service areas.² One of these OPOS, with a large number of minority patients on its waiting list, obtained UNOS approval to eliminate consideration of antigen matching because it believes that antigen matching disadvantages minority patients while having a “lack of relevance on transplant outcome.”³

Table 2.1: Variances to UNOS Criteria for Ranking Kidney Patients

Variance	Number of OPOS ^a
Increases the weight given to those patients on the list the longest.	5
Changes the weight given to matching, except for six-antigen matches.	13
Changes the weight given to highly sensitized patients. ^b	10
Changes the weight given to pediatric patients.	6
Changes other factor(s).	3

^aSome OPOS had more than one variance to the UNOS allocation criteria.

^bHighly sensitized patients are individuals whose immune system makes it difficult for them to receive organs.

Source: Questionnaire responses and UNOS.

¹Evaluation of the Organ Procurement and Transplantation Network, Abt Associates, Inc., (Cambridge, Mass.: 1990), p. 95.

²Some transplant experts do not believe existing data show that antigen matching, for less than six-antigen matches, significantly improves transplant outcomes.

³HLA antigen combinations are genetically inherited and tend to follow racial and ethnic lines. Using HLA antigen matching to allocate kidneys from a predominantly white donor population favors the white patient and disadvantages the black patient.

Table 2.2: Variances to UNOS Criteria
for Ranking Heart Patients

Variance	Number of OPOs ^a
Uses more than two medical urgency categories.	11
Increases the weight given to the distance from the donor.	6
Uses a point system instead of a priority system.	5
Changes other factor(s).	5

^aSome OPOs had more than one variance to the UNOS allocation criteria.

Source: Questionnaire responses and UNOS.

Table 2.3: Variances to UNOS Criteria
for Ranking Liver Patients

Variance	Number of OPOs ^a
Decreases the weight given to patients waiting the longest.	3
Weights the potential recipients' distance from the donor.	3
Increases the weight given to medical urgency.	2

^aSome OPOs had more than one variance to the UNOS allocation criteria.

Source: Questionnaire responses and UNOS.

Another example of a variance to the UNOS criteria relates to the extra weight that UNOS gives for highly sensitized patients; that is, patients whose immune systems make it difficult for them to receive a kidney. The extra weight is intended to increase the chances that such patients will receive a kidney. Federal law requires that the national system match organs, “especially” with highly sensitized patients. However, many transplant experts believe these patients are less likely than nonsensitized patients to have successful transplant outcomes. For example, two transplant centers that obtained approval from UNOS to eliminate any extra weight for highly sensitized patients said “there is a real question as to whether specifically selecting the highly sensitized patient is the best use of a limited resource.” It is unclear, however, whether eliminating any extra weight for highly sensitized patients is consistent with the statutory requirement to match organs “especially” with highly sensitized patients.

Variances to Allocation
Criteria Not Evaluated

The Network contract and federal law require UNOS to conduct studies to improve allocation. UNOS allocation policies are studied by UNOS committees and its board of directors. Neither UNOS, HHS, nor the OPOs have

specifically studied the impact of OPO and transplant center variances.⁴ Some variances are intended to improve the chances of groups of patients considered to be at a disadvantage to receive an organ under the UNOS system. For example, one OPO considered its large minority population to be at a disadvantage using the UNOS antigen matching weight. The OPO decreased the weight given to antigen matching with the objective of improving the chances of its minority patients to be ranked higher on the list. If it can be shown that this variance improves the ranking of minority patients then minority patients with similar characteristics in other OPOs that have not adopted this variance appear to be at a disadvantage.

Until recently, only one of the 25 OPOs with a variance had agreed to evaluate its impact after 1 year as a condition of UNOS approval. More information is needed about the impact of these variances so that UNOS can assess whether OPOs should discontinue their use, encourage other OPOs to adopt them, or incorporate them into the national system.

Recent Actions to Prompt Evaluation of Variances

Recently, UNOS has taken steps to encourage OPOs and transplant centers to evaluate their own variances to the UNOS criteria. In August 1992, UNOS requested all OPOs and transplant centers to submit an evaluation of their variances for review by UNOS's Organ Procurement and Distribution Committee. As of October 15, 1992, nine OPOs had submitted these evaluations.

In addition, in November 1992, UNOS adopted procedures for approving and evaluating future variances to the UNOS criteria. Under these procedures, an OPO's proposal to modify the UNOS criteria must contain a detailed written explanation and justification specifying how the variance will enhance the equity of organ allocations. Subsequent to UNOS approval, an OPO and its area transplant centers must provide UNOS a periodic assessment of the variance's impact and note any allocation problems that may have arisen as a result of the change.

⁴The most recent request for proposals for the continuation of the Network requires development of a plan under which transplant centers can apply for a variance to existing Network policy. This plan shall include a standard format for applying for a variance that includes a research method to evaluate the impact of the variance on organ allocation, patient waiting time, and patient and graft survival.

Higher Ranked Patients Not Always Considered by Some OPOs

Under the allocation system used by some OPOs, not all patients within an OPO's service area have the same opportunity to be considered as a potential recipient for an organ. Although OPOs are required by federal law to allocate organs "equitably . . . according to established medical criteria," we found that about one-third of the OPOs, because they use a transplant center-specific list, exclude from consideration some of the patients in their service area. Under federal law, these exclusions are permissible only if they are based on medical criteria. An example, although rare, is if the OPO service area is so large that the quality of the organ may be jeopardized if sent across the OPOs service area. Our survey leads us to question whether cited reasons for center-specific lists qualify as medical criteria.⁵

Twenty OPOs Sometimes Exclude Service Area Patients From Consideration

We found from our survey of the 68 OPOs that as of December 31, 1991, 20 OPOs reported that they sometimes offer organs to only one transplant center or a group of transplant centers instead of considering all patients in their service areas.⁶ This practice is most common for kidney allocations (occurring at 17 OPOs) where an OPO service area can encompass as many as 14 transplant centers and several hundred patients waiting for transplants. According to our survey, the three most common reasons cited for selecting the transplant center that will give priority to its patients were that (1) the transplant center's patients were located at the same hospital as the organ donor, (2) the transplant center claimed for its patients some or all organs procured from their donor hospitals, and (3) the transplant center's patients were "next in line" according to the OPO's arrangement to rotate priority consideration among its transplant centers.⁷

At one OPO with five transplant centers, priority was rotated among transplant centers according to the number of patients on each center's waiting list. The two transplant centers with the greatest number of patients were each given priority to allocate about one-third of the kidneys

⁵The Organ Transplant Amendments Act of 1988 clarified the requirements for equitable distribution of organs in part because concern arose that OPOs might show favoritism to particular transplant centers. The Congress amended the law to require OPOs "to allocate donated organs equitably among transplant patients according to established medical criteria." Prior to the 1988 amendments the law required equitable allocation "among transplant centers and patients." As a consequence, OPOs may have a heavy burden to demonstrate that geography is a valid consideration in formulation of an organ allocation policy.

⁶Of the 68 OPOs, 53 OPOs serve more than one transplant center in their service area.

⁷Transplant centers may alternate having priority either for (1) all organs procured in a given time period (for example, a week) or (2) only the next available organ/donor (for example, transplant center A has priority for one organ, then transplant center B has priority for the next organ, etc.).

and the three smaller centers were given priority for allocating smaller portions of the available kidneys. This OPO used this rotation system to ensure that smaller transplant centers would be able to perform a minimum number of transplants.

More Highly Ranked Patients Within the OPO Service Area Not Always Considered by Some OPOs

During our site visits to 10 OPOs we found four of them gave priority to patients at a specific transplant center instead of considering all patients in the OPO service area. In a review of the donor files at these OPOs, we found during a 3-month period that higher ranked patients within the OPO's service area (that is, patients who have a greater medical need, have been waiting longer for the organ, or both) are not considered when organs are offered to a transplant-center sublist.

During this period, the four OPOs allocated 199 organs, mostly kidneys, initially using transplant center-specific waiting lists instead of using an OPO-wide waiting list.⁸ For 100 of the allocations, there was insufficient documentation for us to determine whether or not higher ranked patients in the OPO service area were excluded from consideration. Of the remaining 99 transplant center allocations, we identified 69—53 kidney and 16 liver allocations—in which potential recipients on the OPO-wide waiting list had been ranked higher than the recipient, but were not considered because they were not on the transplant center-specific waiting list. In 30 other cases, no higher ranked patients were skipped.

The number of patients who were higher on the OPO-wide waiting list but not considered was particularly high for kidney allocations. Of 53 kidney allocations, 22 had over 100 higher ranked individuals on the OPO-wide waiting list who were not considered. Of these 22, 7 kidney allocations were made in which over 200 more highly ranked patients were overlooked, including one case in which 340 potential recipients were not considered.

A higher ranked patient may have had a better antigen match than the recipient, been waiting longer, and/or had greater medical urgency. While these patients may not be selected for a variety of medical reasons, their chance for an organ, however small, is lost when they are excluded from consideration.

⁸During this same period, these four OPOs allocated a total of 507 organs from 168 donors using both area-wide and transplant center-specific waiting lists.

Many OPOs and Transplant Centers Oppose Use of Transplant Center Waiting Lists

Many transplant centers and OPOs oppose the practice of considering patients at a specific transplant center instead of all of the OPO's patients when allocating organs. A 1990 survey of all Network members (transplant centers, OPOs, and tissue-typing laboratories) found that 78 percent of those responding believe OPOs should use a single, OPO-wide waiting list for allocating organs. Of the OPOs responding, 87 percent favored the use of a single OPO-wide list.^{9, 10} Some OPO officials believe that the primary reason for allowing transplant center-specific lists to be used is to ensure that each transplant center allocate at least a minimum number of organs to its patients. If this is the sole reason for such an arrangement, transplant center equity is placed above patient equity. A 1991 HHS Inspector General report recommended that regulations be issued requiring that each OPO establish a single unified list of patients awaiting transplantation and distribute organs on a first-come-first-served basis subject to established medical criteria.¹¹

Some OPOs or their transplant centers believe that offering organs to a single transplant center is justified in some cases. These OPOs cite several reasons in support of this practice, including the possibility that (1) it may encourage more procurement because surgeons would be more willing to procure kidneys they know they will keep for their own patients; and (2) it enables smaller transplant centers to receive enough organs to be efficient and effective. Given that organs are to be allocated equitably in accordance with medical criteria, however, the only legally acceptable reasons for not allocating organs using an OPO-wide list are those which are based on medical criteria. It is unclear whether the above reasons could legitimately be considered valid medical concerns.

Using an OPO-Wide List Becomes UNOS Policy

In November 1992 UNOS adopted a policy calling for OPOs to use a single OPO-wide list. This new policy, which will take effect on July 1, 1993, states that any deviation from this practice must be approved by UNOS. However, because of voluntary compliance, there is no assurance that all OPOs will comply with such a policy.

In addition, HHS stated that it is preparing a Notice of Proposed Rulemaking to address the matter of multiple waiting lists within an OPO

⁹Sixty percent of transplant centers and 80 percent of OPOs responded to the survey.

¹⁰Evaluation of the Organ Procurement and Transplantation Network, p. 83.

¹¹The Distribution of Organs for Transplantation: Expectations and Practices, U.S. Department of Health and Human Services (Washington, D.C.: 1991), p. 18.

service area, particularly lists that are transplant center-specific. HHS has acknowledged to us that when OPOs use transplant-center specific lists some patients with a higher priority may not be considered for an organ. (See app. II for HHS's August 10, 1992, letter on this topic, and app. III for a summary of differences in OPO's use of single and transplant-center lists and variances to the UNOS allocation criteria for kidney allocation.)

Inadequate Documentation May Raise Questions About OPO Allocation Practices

OPOs cannot assure that they have followed an equitable process in allocating organs when they do not fully document the patient selection process. Although UNOS specifies that OPOs and transplant centers should document reasons why higher ranked patients are skipped or not selected when an organ is allocated, we found that OPOs do not always document these reasons. Typically, during the allocation process, the OPO or transplant center staff, beginning with the highest ranked patient, contacts the patient's transplant surgeon and offers the organ. If the organ is declined, the staff member will note the surgeon's reason for not accepting the organ. Reasons for declining an organ are noted on a UNOS form or on the computer-generated list of patients. This documentation should be retained at the OPO or transplant center. The failure of OPOs to document their allocation decisions hampers HHS's, UNOS' and the OPO's ability to determine whether established allocation policies are being followed or if abuses to the system are occurring.

The Extent OPOs Document the Organ Allocation Process Varies

To determine the extent to which OPOs adhered to the UNOS policy of documenting the patient selection process, we reviewed the files for every donor referred and whose organs were recovered during September, October, and November of 1991 at the 10 OPOs. This included allocations made to patients within the OPO service area, the UNOS region, or nationwide. In some cases, individual transplant centers or the UNOS organ center allocated the organ and, therefore, had the responsibility for documenting the allocation decisions, rather than the OPO.

We reviewed the allocation process for 829 organs from 279 donors. Of these 829 organ allocations, we analyzed the 419 of them in which a patient was skipped to determine the extent to which there were documented reasons for not selecting higher ranked patients.

At the 10 OPOs, the extent of missing documentation ranged from 15 percent of organ allocations at one OPO to 75 percent of organ allocations

at another OPO.¹² In some cases, OPO officials were able to explain from memory why patients were not selected but without documentation the decisionmaking process could not be justified and further analysis for possible patterns of abuse cannot be conducted.

UNOS was directly responsible for allocating and documenting the decisionmaking process for 107 of the 829 organs allocated during our review period. We reviewed UNOS files for 27 of these organs and found that the UNOS allocation decisions were almost always documented.

When reasons for skipping potential transplant recipients were documented, they varied widely. (See app. IV for summary of reasons given for not selecting potential recipients under consideration.) However, the most common reason for not selecting a potential recipient is that he or she had a positive crossmatch with the donor's tissue.¹³ This reason was given for skipping 2,087 individuals, which was 43 percent of all patients skipped for all organs in our sample.

Documentation promotes accountability and enables compliance review. This helps assure that the system will be fair. Documenting adherence to the allocation process is also a necessary step if the OPOS, UNOS, or HHS are to assess potential patterns of abuse in the system or other allocation problems.

HHS Action Hinders UNOS' Ability to Ensure Adherence to Allocation Policies

While UNOS has recently taken steps to monitor the different allocation practices currently in use, without the backing of federal regulations, there is no assurance that OPOS and transplant centers will comply with new policies. Currently, HHS characterizes Network policies as voluntary guidance for OPOS. As a consequence OPOS can choose to comply or not comply.

¹²In determining the extent organ allocations were documented, we considered 419 organ allocations—from 4 allocations at one OPO to 91 at another—in which the highest ranked patient was not selected to receive the organ. If the reason for not selecting one or more higher ranked patients was missing, we considered that allocation not to be adequately documented to justify why the recipient was selected.

¹³A positive crossmatch indicates that the donor's tissue is not compatible with the potential recipient's and the potential recipient would likely reject that organ. Crossmatching typically is used to determine the compatibility of kidney donors and recipients.

HHS Ruled That UNOS Policies Not Considered Binding

During debate on the Organ Transplant Amendments of 1988, concern was raised that because UNOS—a non-federal entity—had promulgated the rules and requirements of the Network, they were not subject to the usual notice and comment requirements and that this may have constitutional implications.¹⁴ The amendments addressed this concern, at least in part, by adding requirements for public comment on Network membership and medical criteria.¹⁵

Regardless of this statutory requirement for public comment on Network rules, because section 1138 of the Social Security Act requires all transplant centers to abide by the rules and requirements of the Network in order to be reimbursed by Medicare or Medicaid, HCFA determined that no rule, requirement, policy, or other issuance of the Network was to be considered a binding “rule or requirement” of the Network unless formally approved by the Secretary of HHS. Furthermore, the notice indicated that no entities could be considered out of compliance with Network membership requirements except as permitted by the Secretary. Since that time, HHS has been in the process of developing proposed regulations.

This action has had the effect of making voluntary the Network policies developed by UNOS. If OPOS and transplant centers choose not to follow Network policies, they risk little or no adverse impact. The comprehensive policies established by UNOS are merely advisory and not binding. Because UNOS presently cannot enforce Network policies, its influence has been diminished.¹⁶

¹⁴Although concern was also voiced during the debate on the 1988 amendments regarding the possible antitrust implications of permitting UNOS to operate the Network and establish membership criteria, the amendments did not directly address that issue.

¹⁵Under the Administrative Procedure Act, federal agencies generally are required to provide the public with notice and an opportunity to comment on rules before they may be adopted and enforced.

¹⁶Although concern was also voiced during the debate on the 1988 amendments regarding the possible antitrust implications of permitting UNOS to operate the Network and establish membership criteria, the amendments did not directly address that issue.

¹⁷Office of the Assistant Secretary for Planning and Evaluation officials indicated to us that HHS was compelled to take this action because many of the policies adopted by UNOS were in conflict with other HHS requirements, otherwise misguided, or beyond the scope of the National Organ Transplant Act. The pending request for proposals to operate the Network incorporates a variety of procedural safeguards and controls expressly permitting HHS to provide timely guidance to, and retain effective control over, operation of the Network. Apparently, because the initial contract was less comprehensive, it did not facilitate sufficient guidance by HHS to prevent UNOS from promulgating unacceptable policies.

OPOs Not Assessed on Ability to Obtain Available Organs

Organ donation relies on the cooperation and dedication of the medical community to identify and refer potential donors and the generosity and compassion of family members to consent to organ donation at a time of great personal loss. Many potential donors are lost during the time that decisions to donate organs could be made. For this reason, the actual number of donors is far less than the number of potential donors. Although the importance of organ donation is recognized by physicians and other hospital staff, medical personnel may be reluctant to approach families about donating their relatives' organs because they are not comfortable broaching the subject, because it is time consuming, or because they believe it would unduly burden the family.

OPOS work with the medical community and the public through professional education and public awareness efforts to encourage cooperation in and acceptance of the idea of organ donation. Nevertheless, the wide variation in OPO rates for procuring organs—from 1 to 32 donors per million population—suggests that some OPOS could be more effective.

HHS and UNOS have oversight responsibilities for OPO procurement activities. More specifically, as HHS's designated administrative unit, HHS is required by law to provide technical assistance to the OPOS. However, neither organization has assessed OPO performance in procuring organs, and neither has developed or adopted a standard by which to measure procurement effectiveness. As a result, HHS has not been in a position to determine which OPOS have the greatest need for technical assistance.

Different OPO Practices Could Account for Procurement Rate Differences

The procurement rate is the number of donors per million population that an OPO has obtained in its service area. The 68 OPOS vary widely in the number of donors procured per million population within their service area. However, because of the different characteristics of the OPOS, this procurement rate alone should not be considered an adequate measure of procurement effectiveness. In responding to our questionnaire, the OPOS reported annual donor procurement rates ranging from 1 to 32 donors per million population in 1990 and 1991.¹ The OPOS averaged 19 donors per million population during those years. (App. V shows the number of donors per million population for each OPO for 1991.) There was also variation among OPOS in the organ procurement rate. The OPOS reported procuring annually between 2 and 110 organs per million population in

¹We calculated procurement per million by dividing the OPO's questionnaire response for donors procured by the OPO's service area population as reported by HCFA to UNOS.

1990 and 1991, with an average of about 62 organs per million population procured each year by each OPO. Nine of the 68 OPOs annually averaged fewer than 40 organs per million population for the 2 years, while 17 OPOs averaged at least 80 organs per million population.

Inherent differences between OPO populations, such as the rate of death, rate of communicable disease, and willingness of the population to donate organs, may explain some of the differences in OPO procurement rates. However, a study has reported differences in the efficiency of different OPOs in obtaining the available potential donors.² Further, HRSA and UNOS agree that individual OPO policies, initiatives, and methods for obtaining organs probably contribute to the variation in organ procurement rates.

OPOs Have Established Their Own Donor Acceptance Criteria

Differences in donor acceptance criteria may be one factor accounting for the variation in donor procurement rates. OPOs generally have established minimum and maximum ages for acceptable donors and have specified certain diseases that would preclude acceptance of a donor. Responses to our questionnaire showed that these criteria vary among OPOs.

The benefit of increased organ supply resulting from broadening the criteria for donors must be balanced against the increased risk of using marginal organs. Marginal donors, those not routinely considered as organ donors, include older individuals, non-heart beating donors, diabetics, donors with systemic infections or abnormal organ function, and those with certain other medical problems. The use of such marginal donors can enlarge the donor pool and benefit patients that otherwise would not receive a transplant. However, the use of organs from these donors increases the risk of complications or death for the recipient.

Most OPOs have age criteria for accepting donors. Among the 57 OPOs reporting that they have established a maximum acceptable age, the criteria vary, with the maximum age of acceptable donors ranging from 60 to 90 years old. Fourteen of the OPOs reported that their maximum age was 75 or over; 31 of the OPOs established from 70 to 74 as the maximum age; and 12 OPOs reported that their maximum age was between 60 and 65.

OPOs also have different criteria for accepting donors with certain diseases. For example, 44 OPOs will accept donors with hepatitis C, and 13 OPOs will accept donors with certain cancers.

²R.W. Evans, C.E. Orians, and N.L. Ascher, "The Potential Supply of Organ Donors," *Journal of the American Medical Association*, Vol. 267, No. 2 (Jan. 8, 1992), pp. 239-46.

Choice of Staff to Obtain Consent for Organ Donation Differs Among OPOs

The OPOs' and hospitals' choice of staff to explain the donation option and request donations may differ from OPO to OPO. Obtaining consent may depend on the requester's professional background, training, race, and personal characteristics. In many instances, donor hospital staff approach the family to gain consent for donation, while in others the consent process is handled by an OPO staff member. For example, in responding to our questionnaire, 16 OPOs reported that in over 80 percent of organ donor referrals in 1991 their OPO staff asked the potential donor family for consent to donate. However, another 19 OPOs responded that their staff made the request of the family in 40 percent or fewer of the 1991 referrals. The extent to which choice of staff affects the success rate in obtaining organs is unclear.

OPOs Use Different Techniques to Increase Organ Procurement

At the 10 OPOs we visited, we found similarities in the techniques used to enhance organ procurement efforts and increase the supply of organs. All 10 OPOs had programs to provide professional education on organ donation to health care providers. Also, they all conducted public awareness activities to increase public acceptance of organ donation. (App. VII discusses potential changes to national policy and improvements in technology that have been suggested by various experts to increase the supply of organs for transplants.)

A public awareness activity at one OPO we visited was to join a coalition of organ and tissue transplant programs in the state to support a program with goals that include increasing the public's knowledge of donation. The coalition, working with the state's motor vehicle division, increased the number of drivers with donor cards by 11 percent in the year ending June 30, 1991.³ The coalition also operates a speakers bureau to encourage donation and provides education to groups involved in identifying and referring donors.

Another OPO's professional education efforts included establishing donor councils at many of its major hospitals. The donor councils, multidisciplinary teams of hospital and OPO staff, work to improve the organ donation process by identifying and eliminating impediments to identifying potential donors and assuring a consistent, sensitive approach to families regarding organ donation.

³Completion of donor cards typically does not guarantee that those who complete them will become potential donors because medical authorities typically do not honor donor cards over objections by family members. See James F. Blunstein, "Government's Role in Organ Transplantation Policy," *Journal of Health Politics, Policy, and Law*, Vol. 14, No. 1 (Spring 1989), p. 29 for a brief critique.

A third OPO we visited, to assist both the public and health care workers, developed a book explaining brain injury and the brain death diagnosis. The book is intended for use by physicians, nurses, and others who talk with head injury patients or their families. The OPO provided this book (translated into several languages) to each intensive care unit in its service area and to other OPOs.

Some OPOs Target Donations by Minorities

A greater proportion of blacks and certain other minorities suffer from kidney failure than do whites. However, contributions of kidneys by blacks and other minorities are often not in proportion to the need that exists or their representation in the population. For example, in 1990 blacks made up 12 percent of the U.S. population, represented about one-third of the patients waiting for kidney transplants, but accounted for only 9 percent of the kidney donors. Increasing organ donation by certain racial or ethnic groups benefits similar groups on the waiting list because genetically there is a greater likelihood of donor compatibility.

Some OPOs believe that having racially and ethnically diverse staff trained in being sensitive to the concerns of minority families can be beneficial in increasing minority donations.⁴ In the responses to our questionnaire, 21 of the 68 OPOs employed minorities to request organ donations. About one-third of the OPOs responded that their OPO did not train its staff in how to approach racial or ethnic minority families for organ donations. Because of the racial and ethnic composition of the population in their service area, some OPOs may not see a need to emphasize organ donations by minorities.

Most OPOs Collect Data on Their Organ Procurement Process

Most OPOs collect some data on aspects of the organ procurement process. Data are collected on the extent to which potential donors are identified, whether consent for donation is granted, and other data, such as who requested donation. The extent to which OPOs collect data varies and, therefore, their ability to assess their own procurement effectiveness also varies. HRSA has not provided guidance to the OPOs on assessment criteria nor have they requested OPOs to provide any of the data the OPOs collect.

⁴Participants at the July 1991 Surgeon General's Workshop on Increasing Organ Donation emphasized the need to increase organ donation by minorities. Among the recommendations to increase donation by minorities was that transplant centers, OPOs, and hospitals hire culturally sensitive and ethnically similar transplant coordinators and other personnel.

Moreover, HRSA has not required UNOS, through its contract, to perform these tasks.⁵

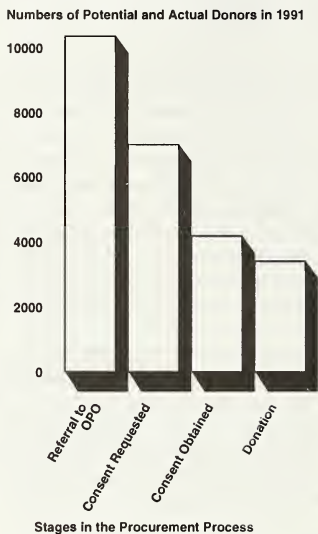
Many Identified Potential Donors Do Not Become Organ Donors

The organ procurement process has three critical phases: first a potential donor must be identified, usually by donor hospital staff, and assessed as a viable donor; second, the potential donor's family must be approached and give consent to donate; and third, the organs need to be retrieved by transplant or other surgeons. During the process, the number of potential donors becomes progressively smaller. Many potential donors referred to the OPO do not meet its acceptance criteria, while for others, the donor's family does not consent to donation. Additionally, after donor consent is obtained, some potential donors are found to have diseases or physical conditions that make their organs unusable.

Of the 68 OPOs responding to our survey, 53 reported to us the number of potential donors referred to their OPO, the number for which consent for donation was requested and obtained, and the number which ultimately were organ donors. At those 53 OPOs, during 1991, donor hospitals referred 10,341 potential donors. Of these, consent was requested for 6,983 and obtained for 4,158 of them. Ultimately, 3,396 of them became organ donors. (See fig. 3.1.)

⁵The latest request for proposals for the continuation of the Network calls for the contractor to develop a standardized death audit methodology to be used by the OPOs to determine the number of potential donors annually.

Figure 3.1: Reduction of the Donor Pool During the Organ Donation Process



Note: Only data from OPOs responding to all stages of the procurement process are included.

The Extent OPOs Collect Procurement Process Data Varies

The OPOs that assess their own organ procurement efforts either attempt to determine if potential donors are being identified or how successful the OPO is in gaining consent from families. Some OPOs perform both assessments.

Most OPOs review hospital medical records to assess the number of potential donors at individual hospitals and the extent to which these potential donors were identified. Of the 68 OPOs we surveyed, 60 stated that they had performed some type of medical records review. Of the 10 OPOs we visited, 9 performed medical records reviews. These varied from a yearly review of all major hospitals to a review of a sample of charts at some major hospitals. Most OPOs believe that medical records reviews were very useful in determining the efficiency of their procurement efforts at hospitals, according to questionnaire responses.

Additionally, many OPOs collect data to assist them in determining their effectiveness during the donation consent process. With no established requirements for the collection of such information, the OPOs decide what type of information to collect. Table 3.1 shows the number of OPOs that collect certain information that can help the OPO assess organ procurement effectiveness.

**Table 3.1: Information Collected by
OPOs on Potential Organ Donors
Referred During 1991**

Information that indicated	OPOs that usually collected this information	OPOs that did not usually collect this information
Who first initiated the subject of organ donation with the family.	40	28
Whether or not consent was requested.	64	4
Why consent was not requested.	58	9
Who requested consent for organ donation.	55	13
Whether the request was made at the same time that brain death was explained to the family.	20	48
Whether the request was made in a separate discussion sometime after brain death had been explained to the family.	21	47
Whether consent was given or denied.	67	1
Why consent was denied.	49	19
What is the race or ethnicity of the potential organ donor.	62	6

While UNOS officials agree with us that medical records reviews and the collection of other organ procurement process information may be useful in assessing organ procurement effectiveness, UNOS has not been charged, through its contract, with responsibility to ask that OPOs uniformly collect and report this information. The officials stated that while UNOS would view such an effort favorably, they have not been asked to collect such data. Furthermore, since compliance with its policies is voluntary, these officials were skeptical that OPOs would collect and report such information.

HHS Not Adequately Assessing OPO Procurement Efforts and Effectiveness

Procurement effectiveness is the extent to which OPOs are procuring organs from potential donors within their area. No administrative unit within HHS is assessing the effectiveness of the OPOs' organ procurement efforts, nor has UNOS been charged with this responsibility.⁶ Consequently, HHS does not know which OPOs are the most or the least effective at procuring organs.

HCFA Standard for Measuring Procurement Does Not Adjust for Various Sizes of OPO Donor Pools

Essential to determining OPO procurement effectiveness is the development of an adequate measure by which to judge an OPO's procurement effectiveness. Knowing the size of the potential donor pool is important in assessing how well OPOs are performing their organ procurement responsibilities. Widely varying estimates have been made about the size of the national donor pool and the size of the OPOs' donor pools are unknown. Estimates of the national donor pool range from 5,000 to 29,000 donors per year.

Although variation in the OPOs' geographical areas and demographics complicate the development of an effectiveness measure, methods have been developed and applied by others. HHS has neither developed nor adopted an adequate procurement effectiveness measure.

HCFA regulations set performance standards that specify a minimum procurement standard that OPOs must meet in order to be certified as an OPO and be eligible to receive Medicare and Medicaid payments. HCFA regulations require each OPO to procure at least 23 kidneys per million population in their service areas each year in order to be certified.⁷

Because the number of potential donors per million population varies across OPOs, an OPO's achievement of HCFA's minimum standard does not necessarily demonstrate that an OPO was effective in obtaining available organ donors. The HCFA measure of kidneys obtained per million population is designed to assure OPOs achieve minimum organ procurement levels. The standard does not allow HCFA to assess if an OPO is

⁶UNOS recently conducted a survey of OPOs to determine how OPOs function and the impact on organ procurement rates. UNOS published the results of the survey in the September 1992 edition of its monthly publication "UNOS Update."

⁷HCFA relies on OPO self-certification statements to assure compliance with, among other things, that the OPO has met the standard to procure at least 23 kidneys per million population. However, HCFA has taken little action to verify that OPOs meet the kidney procurement standard. Some OPOs did not procure the required number of kidneys from 1990 through 1991, but HCFA certified most of these OPOs as being in compliance with its requirements.

systematically trying to acquire all useable organs from potential donors, as required by the National Organ Transplant Act.

HRSA and UNOS Have Not Adopted an Effectiveness Measure

Although UNOS asks OPOs to report the number of donors and organs they obtain, this information is inadequate to assess procurement effectiveness. HRSA and UNOS have not developed uniform criteria or standards for assessing the OPOs' procurement effectiveness. Neither its existing contract with UNOS nor its current request for proposals ask the Network contractor to develop a measure of OPO procurement effectiveness, nor has the contractor been directed to monitor OPO procurement effectiveness.

One of the complicating factors in developing an accurate measure of OPO procurement effectiveness is that the size of the potential donor pool in each OPO's service area is unknown. HRSA has funded studies of the potential donor pool in three states, but the results cannot be used in other areas because of differences in the populations. The UNOS Donor Availability Subcommittee has recommended that each OPO identify its potential donor pool. The subcommittee, however, did not prescribe methods to accomplish this.

Another factor making it difficult to accurately assess the OPOs' effectiveness in procuring organs is that some OPOs receive donor referrals from hospitals outside of their service area. The law requires HHS to designate only one OPO per service area and requires OPOs to have donor referral agreements with a substantial majority of the hospitals within that service area. However, HHS allows hospitals to have agreements with OPOs serving other areas. (See app. VIII for HHS's April 10, 1992, letter explaining its rationale for this determination.)

In response to our questionnaire, 20 OPOs reported obtaining 162 donors from hospitals outside their service areas in 1991. Twenty-three OPOs reported that some hospitals in their service area had referred or agreed to refer donors to another OPO and 32 OPOs said they had obtained potential donor referrals from or had agreements with hospitals outside their area during that year. This practice complicates the assessment of OPO effectiveness in obtaining organs from available potential donors.

Another difficulty is that populations vary in the incidence of death and disease. For example, large urban areas normally have a higher incidence of patients with AIDS and hepatitis B than do rural areas. Patients with

these diseases are not considered as organ donors, thereby decreasing the potential donor pool in these areas.

Despite these complications, the development of criteria or standards to obtain some measure of OPO procurement performance is possible. One recent study developed a measure of OPO procurement effectiveness based on the number of actual donors compared to an estimate of the potential donors available.⁸ This study developed estimates of the number of potential donors by analyzing cause of death and sociodemographic data for 1988 and 1989 compiled by the National Center for Health Statistics. The study then compared the estimates of the number of potential organ donors to those actually obtained by all OPOs for 1988 and 1989.

The study found the efficiency of OPOs varied considerably, with some OPOs obtaining less than 25 percent of the estimated number of potential donors while others obtained over 100 percent of the estimated available donors.⁹ The accuracy of these potential donor estimates depends in part on the accuracy of the death records. However, the authors point out that this method judges OPOs by a common measure of efficiency that could be updated annually. These estimates also identify those OPOs where donor procurement has the greatest potential for improvement.

Technical Assistance Not Targeted to Problem OPOs

UNOS has conducted a variety of activities to increase organ donations, including providing some technical assistance directly to OPOs. However, UNOS has not targeted such assistance or given special priority to OPOs with low procurement effectiveness. UNOS cannot do so because it has not assessed the procurement effectiveness of individual OPOs. Table 3.2 lists some of UNOS's activities intended to increase organ donations.

⁸Evans and others, pp. 239-46.

⁹The authors defined efficiency as a percentage of estimated potential donors who became organ donors.

Chapter 3
OPOs Not Assessed on Ability to Obtain
Available Organs

Table 3.2: UNOS Activities to Promote Organ Donation.

Categories	Purpose	Activity
Professional education	To target educational efforts to health professionals to remove perceived and real barriers to organ and tissue donation.	<p>Six major projects</p> <ol style="list-style-type: none"> 1. Initiated program to increase neurosurgeon involvement in the donation process 2. Developed medical school curriculum 3. Developed nursing school curriculum 4. Published reference manual on organ procurement and transplantation 5. Held workshops to improve transplant coordinator skills 6. Contributed to the Surgeon General's Workshop
Public education	To target education efforts to the public to increase understanding of organ donation and transplantation and to increase the public's willingness to donate.	<p>Six major projects</p> <ol style="list-style-type: none"> 1. Helped form the Coalition on Donation to develop an education campaign 2. Operates 1-800-24-DONOR, a 24-hour toll free telephone line to provide donor information 3. Distributes brochures providing donor information 4. Developing the National Transplantation Resource Center 5. Joined an exhibit consortium to conduct joint exhibits 6. Conducts donor family support activities
Organ procurement organization activities	To improve the efficiency and effectiveness of OPOs in obtaining organs.	<p>Three major projects</p> <ol style="list-style-type: none"> 1. Designing workshop to improve procurement coordinator hiring 2. Planning study of routine referral and routine inquiry 3. Conducts OPO forums to exchange information
Other activities	To identify and suggest remedies to other impediments to organ procurement.	<p>Three major projects</p> <ol style="list-style-type: none"> 1. Study on expanded donor criteria 2. National public survey on creative alternatives 3. Focus group on creative alternatives

HRSA conducts a number of activities to increase organ donations. HRSA provides public information on the need for organ donation and maintains working relationships with professional organizations to promote organ donation. HRSA also has a program that awards grants to individual OPOs or other organizations for projects intended to increase donations. Many more grant applications are received than can be funded, HRSA officials told us. After a technical review process, grants are awarded to organizations for projects designed to increase organ donations, the officials said. Grant funds have been awarded to 47 OPOs from fiscal year 86 through fiscal year 92. Table 3.3 lists some of HRSA's activities intended to increase organ donations.

Table 3.3: HRSA Activities Intended to Increase Organ Donation

Activity	Purpose	Description		
		Fiscal year	No. of grants	Total amount
Grant program	Initially grants were intended to consolidate organ procurement programs. Since 1989, grants have emphasized increasing organ donation, specifically minority donations.	HRSA awarded the following grants, primarily to OPOs:		
		92	10	\$400,000
		91	9	308,000
		90	8	492,000
		89	9	485,000
		88	18	1,300,000
		87	18	2,700,000
		86	18	2,000,000
Exhibit program	To promote organ donations at meetings of various local and national organizations.	Established in 1986. Participated in about 35 conferences and meetings in 1991. HRSA has exhibits at Washington, D.C., area gatherings. HRSA also provides materials to OPOs for meetings in their areas.		
National Organ and Tissue Donor Awareness Week	To coordinate federal activities related to Donor Awareness Week, which promotes the need for organ donations for one week each spring.	HRSA has coordinated federal involvement since 1987.		
Surgeon General's Workshop	To develop recommendations and strategies for increasing organ donation.	The July 8-10, 1991, workshop included 125 participants with diverse backgrounds. After discussing issues, participants made recommendations on how to increase organ donation. The Public Health Service has published the proceedings and background papers.		
Department of Organ Transplantation Annual Meeting	To bring together transplant professionals from across the country to discuss current transplant issues.	These meetings have been conducted annually since 1988.		

Conclusions and Recommendations

Conclusions

HHS, UNOS, OPOS and transplant centers are faced with making difficult decisions on how best to distribute the limited supply of organs. When developing organ distribution policy, several factors may be relevant: fairness to patients, who have often waited months and years for a transplant; the urgent needs of patients who will soon die without a transplant; and the likelihood that selected patients will survive a reasonable amount of time with an acceptable quality of life. Another challenge is to increase the supply of organs so that more patients can be given the opportunity to benefit from transplantation. Studies have estimated a potential donor pool that far exceeds the number of donors that OPOS have obtained. However, potential organ donors are lost during the organ donation process for several reasons, including not being identified as a possible donor or consent for donation not being granted.

The Organ Procurement and Transplantation Network, as prescribed by law, has established an organ allocation system which, although not binding, lays out the criteria and the weight to be given to each criterion when ranking patients waiting for an organ. Some OPOS and transplant centers have changed the weight given to certain criteria, thus giving an advantage to groups of patients who would otherwise have a lesser chance of receiving an organ. Because the debate continues on how best to select patients to receive an organ, variances need to be systematically considered for approval and evaluated to determine their impact on patients. However to date, HHS and UNOS have not done this. Not studying these practices deprives the transplant community of the opportunity to gain more uniform agreement on how best to allocate organs.

Because of an allocation practice that favors transplant centers over patients, some OPOS, when allocating organs, will exclude from initial consideration patients ranked higher than the recipient. Medical criteria may necessitate the exclusion of some patients at certain transplant centers when allocating organs. We question, however, the appropriateness of using transplant center-specific waiting lists in OPOS that serve several transplant centers in the same metropolitan area. Favoring transplant centers over the needs of patients is contrary to federal law. Additionally, broadening the number of patients considered for an organ may result in selecting a patient who is better suited for the organ or has been waiting longer.

One way to help ensure that decisions regarding who receives an organ are fair is to document that OPOS and transplant centers are following established organ allocation guidelines. OPOS do not always document the

reasons why patients have been denied an organ. While the lack of documentation does not necessarily indicate inequitable allocation, it may raise questions regarding fair treatment of patients. If the Network, OPOS, and transplant centers cannot demonstrate that their decisionmaking process followed established guidelines, the public perception of the equity of the organ allocation system may be compromised. Documentation of the allocation process is also a necessary step if HRSA, UNOS, or the OPO chooses to monitor the system for (1) adherence to established allocation policies and (2) abuses to the system.

While UNOS and HRSA have taken steps to correct some of the above problems, the voluntary nature of the Network's organ allocation policies hinders UNOS ability to ensure an equitable allocation system as intended by law. According to HRSA and UNOS officials, OPO compliance to UNOS rules is high. However, we found that some OPOS (1) have deviated from UNOS allocation criteria without following the UNOS approval process and (2) do not always document their allocation decisions.

With the growing demand for transplantation and the shortage of organs, efforts to increase the supply are vital. OPOS are the primary procurers of organs and are responsible for retrieving the greatest number of organs from the donor pool. Because of the vast differences in the rate of organs each OPO procures, we believe more needs to be done to assist OPOS in meeting their organ procurement responsibilities.

HRSA and UNOS have oversight of the OPOS' organ procurement efforts, but neither has made an effort to assess the OPOS' procurement effectiveness and, therefore, do not know which OPOS are falling short of meeting their responsibility. One of the major obstacles in monitoring the OPOS is that a procurement effectiveness measure has not been developed or adopted.

To assist patients waiting for an organ transplant, HRSA needs to take the lead in monitoring the national organ procurement system. Establishing a measure for assessing OPO procurement effectiveness will be key to this effort. Once this is done, HRSA can assist those OPOS that are not meeting their organ procurement potential.

Recommendations

To better ensure that organs are allocated equitably to recipients under a national system as envisioned by the Congress, we recommend that the Secretary of Health and Human Services direct the Assistant Secretary for Health to:

1. Require OPOs and transplant centers to:

- use established Network criteria for ranking patients unless a variance to these criteria has been approved;
- use a single, OPO-wide waiting list for allocating organs unless the OPO can demonstrate compelling medical reasons for doing otherwise; and
- document the reasons for not selecting potential recipients ranked higher on a waiting list than the patient to whom the organ was allocated.

2. Require an evaluation of variances to the UNOS allocation criteria to determine if they (1) are achieving intended goals and (2) should be incorporated into the UNOS criteria.

To increase the effectiveness of OPOs in procuring organs for transplants, we recommend that the Secretary of Health and Human Services direct the Assistant Secretary for Health to:

1. Establish criteria for assessing OPO organ procurement effectiveness.
2. Target technical assistance to those OPOs identified as least effective in procuring organs.

UNOS Criteria for Ranking Patients Waiting for Organ Transplants

The UNOS Board of Directors has established national criteria for ranking individuals waiting for organ transplants. UNOS adopted the original criteria in 1987. Since then, the criteria have been amended several times to accommodate changing technology and recent data. Below are descriptions of the current ranking criteria for patients waiting for a kidney, heart, or liver transplant. The ranking system gives first priority to patients in the OPO service area, then to patients in the region, then to patients nationally.¹

Allocation policies and amendments to current allocation policies go through UNOS committees before the UNOS Board of Directors considers them. Policy proposals are accompanied by a description of the underlying rationale and, where applicable, a summary of medical, ethical, and scientific evidence upon which the proposed policy is based. Before final approval, policy statements approved by the Board are distributed to HRSA, UNOS members, and other interested persons and are made available to the general public. Following a 45-day comment period, the appropriate committee(s) reviews and amends the policy as it deems necessary, then resubmits the amended policy proposal to the Board of Directors for a final vote.

Kidney Ranking System

Patients anywhere in the country with a six-antigen match² and compatible blood type are listed together ahead of other patients. Then other patients on kidney transplant waiting list(s) are considered for a kidney in descending point sequence based on the following criteria:

Waiting Time: A kidney transplant candidate's priority on the waiting list is determined from the date of the candidate's activation on the UNOS computer system. One point is given to the candidate waiting for the longest period with fractions of points received by those candidates with shorter tenure. An additional .5 points are awarded for each additional year after one year of waiting time is accrued.

¹At some OPOs, the transplant centers, using established criteria, prioritize and allocate organs first to their own patients. UNOS allows OPOs and transplant centers to adjust the allocation criteria.

²UNOS defines a six-antigen match as six HLA antigens of the donor either (1) matching perfectly with those of the potential recipient or (2) being phenotypically (apparently) identical to those of the potential recipient.

Quality of Match:³ Points are awarded based on the degree of antigen mismatches for a possible total of 10 points. The points awarded and the degree of antigen mismatch are as follows:

- 10 points, no (A, B, DR) mismatch;
- 7 points, no (B, DR) mismatch;
- 6 points, no (A, B) mismatch;
- 3 points, 1 (B, DR) mismatch;
- 2 points, 2 (B, DR) mismatch; and
- 1 point, 3 (B, DR) mismatch.

Highly Sensitized: Highly sensitized kidney transplant candidates that have a preliminary negative crossmatch⁴ accrue 4 points.

Blood Type:⁵ Blood group O kidneys shall be transplanted only into blood group O patients except in the case of six antigen matched patients.

Medical Urgency: UNOS does not determine medical urgency for kidney patients nor does it assign points for this category. According to a UNOS official, points that are given for medical urgency are given at the discretion of the local physician(s).

Pediatric Recipients: A recipient 0-5 years of age receives two additional points. A recipient 6-10 years of age receives one additional point.

Heart Allocation

Patients on a heart transplant waiting list are offered hearts in descending priority based on the following criteria:

Status 1: A heart candidate placed in the most medically urgent category, Status 1, is defined as a patient who (1) requires the assistance of a device such as an artificial heart or ventilator; (2) is located in an intensive care unit and requires specific medications to maintain adequate cardiac output; or (3) is less than 6 months old. Within this category, patients of all compatible blood types are ranked in order of their length of time waiting.

³In determining matches, the A, B, and DR human leukocyte-associated (HLA) antigens are used. Every human being has 6 of these antigens (2A, 2B, and 2DR)—three inherited from each parent.

⁴A negative crossmatch result indicates that the potential recipient will not immediately reject the organ.

⁵There are four blood types, A, B, AB, and O. Organs may be transplanted into patients with (1) the identical blood type as the donor or (2) a compatible blood type.

Status 2: The Status 2 medical urgency category includes all other candidates who do not meet the Status 1 criteria. Within this category, patients with the same blood type as the donor are ranked higher than patients with compatible blood types. Patients are further ranked in order of length of time waiting.

Liver Allocation

Patients on a liver transplant waiting list are offered livers in descending order based on the following criteria:

Status 4: Liver patients placed in the most urgent category, Status 4, are listed ahead of those patients listed at lower status codes. Time waiting for Status 4 liver patients is calculated from the time the patients are assigned a Status 4.

Blood Type: Candidates with the same blood type as the donor receive 10 points. Those patients with compatible but not identical types get 5 points, and those with incompatible types do not get points for blood type.

Time Waiting: A liver transplant candidate's waiting time begins at the time the candidate is activated on the UNOS computer. Ten points are awarded to the candidate waiting the longest with fewer points for those patients with shorter tenure.

Degree of Medical Urgency: Points are awarded to a liver transplant candidate for the following categories of medical urgency:

- 0 points, temporarily unsuitable or status 7;
- 6 points, at home, functioning normally or status 1;
- 12 points, receiving continuous medical care or status 2;
- 18 points, continuously hospitalized or status 3; and
- 24 points, life expectancy less than 7 days or status 4.

Preliminary Stratification: For every potential liver recipient, the responsible surgeon must determine a range of acceptable donor sizes, that is, the weight of the donor.

HHS Letter Stating Their Position on OPOs' Use of Transplant Center-Specific Lists



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

AUG 10 1992

Mr. Barry R. Bedrick
Associate General Counsel
United States
General Accounting Office
Washington, D.C. 20548

Dear Mr. Bedrick:

Thank you for your letter of June 17 to Secretary Sullivan regarding organ procurement organizations (OPOs) that do not allocate organs solely on the basis of medical need. As you have noted, where an individual transplant center retains an organ for one of its patients, the result may be that another patient within the same geographic area who has a greater medical need will not be given the organ.

In considering the problem, it is important to know that the present policies of the Organ Procurement and Transplantation Network (OPTN), promulgated by the United Network for Organ Sharing (UNOS), are voluntary. According to the enclosed general notice (FR, December 18, 1989), the Department announced that, for "rules and requirements" of the OPTN to be binding on OPOs and transplant hospitals under Section 1138 of the Social Security Act, they must be published by the Secretary as rules in the Federal Register. Nevertheless, the organ allocation policies developed for the OPTN by UNOS are all designed with medical need as the principal factor in determining the recipient of a donated organ.

The apparent inconsistency arises from the use of transplant center-specific waiting lists of transplant candidates which cover a smaller area than the OPO's service area. Although allocation to potential recipients on such lists are also made on the basis of medical need, transplant candidates elsewhere who are not on a particular center-specific list may in fact have a greater medical need.

The Department is currently preparing a Notice of Proposed Rulemaking (NPRM) governing certain aspects of the OPTN. Consistent with the 1991 Inspector General's Report on The Distribution of Organs for Transplantation: Expectations and Practices, the NPRM will address the matter of multiple waiting lists, particularly lists which are transplant center-specific. We agree about the importance of addressing an equitable method of allocating scarce donor organs based on established medical criteria.

Appendix II
HHS Letter Stating Their Position on OPOs'
Use of Transplant Center-Specific Lists

Page 2 - Mr. Barry R. Bedrick

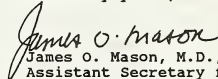
Further, the UNOS Board of Directors, at its most recent meeting of June 24-25, voted to conduct a study to determine the largest area for which organ allocation would be feasible. This study could lead to a standard size of a geographic and demographic area for allocating organs to transplant candidates.

In preparing the final regulations, the Department will consider public comment in response to the NPRM on this issue, and also the UNOS study findings if they are available. If they are not available until after publication of the final regulations, the regulations can be modified as appropriate.

We agree that the OPTN must assist OPOs to allocate organs as effectively and equitably as possible, in accordance with Section 371(b)(3)(E) of the Public Health Service Act. We believe that both the new regulations and the UNOS study will help to accomplish that end.

If you have further questions, please let me know.

Sincerely yours,


James O. Mason, M.D., Dr.P.H.
Assistant Secretary for Health

Enclosure

Variations in OPO Kidney Allocation

Organ procurement organizations	Number of kidney transplant centers that listed patients with the OPO	Allocation system			Modifications to national ranking criteria
		OPO-wide list ^a	Transplant center list ^b	Subset of OPO list ^c	
Alabama Regional Organ and Tissue Center	2	X	•	•	•
Albany Medical College	1	X	•	•	•
Arizona Organ Bank	6	X	•	•	•
Carolinas Medical Center	1	X	•	•	•
Central Texas Organ Program	1	X	•	•	•
Colorado Organ Recovery Systems	4	X	•	•	•
Froedtert Memorial Lutheran Hospital	2	X	•	•	•
Golden State Transplant Services	2	X	•	•	•
Hartford Hospital OPO	1	X	•	•	•
Hawaii Organ Procurement Organization	1	X	•	•	•
Hillcrest Health Care System OPO	1	X	•	•	•
Indiana Organ Procurement Organization	2	X	•	•	•
Intermountain Organ Recovery	2	X	•	•	•
Kentucky Organ Donor Affiliates	3	X	•	•	L, M, H
Life Connection of Ohio	2	X	•	•	•
Life Resources Regional Donor Center	1	X	•	•	•
Lifeline of Ohio	2	X	•	•	L, H, P, O
LifeLink of Southwest Florida	1	X	•	•	M, H
LifeLink of Florida	2	X	•	•	M, H
LifeLink of Georgia	3	X	•	•	•
Louisiana Organ Procurement Agency	6	X	•	•	P
Medical College of Georgia	1	X	•	•	•
Mid-America Transplant Association	5	X	•	•	•
Mid-South Transplant Foundation	2	X	•	•	•
Nebraska Organ Retrieval System	3	X	•	•	•
Nevada Donor Organ Recovery	2	X	•	•	•
New Mexico Donor Program	2	X	•	•	•
New York Regional Transplant Program	8	X	•	•	•
Northwest Kidney Center	4	X	•	•	•
Ohio Valley Procurement Center	3	X	•	•	•
OPO of North Carolina Baptist Hospital	1	X	•	•	•
Organ and Tissue Acquisition Center	2	X	•	•	•
Pacific Northwest Transplant Bank	1	X	•	•	H
Pittsburgh Transplant Foundation	4	X	•	•	•
Puerto Rico Transplant Office	1	X	•	•	•
Regional Organ Bank of Illinois	8	X	•	•	L, M, H

(continued)

Appendix III
Variations in OPO Kidney Allocation

Organ procurement organizations	Number of kidney transplant centers that listed patients with the OPO	Allocation system			Modifications to national ranking criteria
		OPO-wide list ^a	Transplant center list ^b	Subset of OPO list ^c	
Regional Organ Procurement Agency of Southern California	14	X	•	•	M
Sacred Heart Medical Center	1	X	•	•	•
Southern California Organ Procurement and Preservation Center	4	X	•	•	M
South Carolina Organ Procurement Agency	1	X	•	•	•
Stony Brook Transplantation Services	1	X	•	•	•
Translife, East Central Florida Transplant Program	1	X	•	•	M, H
Transplant Resource Center of Maryland	3	X	•	•	•
University of Florida	2	X	•	•	M, H
University of Miami OPO	1	X			M, H
University of Mississippi Medical Center	1	X	•	•	•
University of Rochester Medical Center	2	X	•	•	•
University of Wisconsin Hospital	1	X	•	•	P
Upstate New York Transplant Services	3	X	•	•	•
Virginia Organ Procurement Agency	2	X	•	•	•
Washington Regional Transplant Consortium	7	X	•	•	•
Arkansas Regional Organ Recovery Agency	3	•	X	•	•
California Transplant Donor Network ^d	5	•	X	•	M, H, O
South Texas Organ Bank	3	•	X	•	•
Carolina Organ Procurement Agency	3	X	X	•	•
Delaware Valley Transplant Program	9	X	X	•	•
Iowa Statewide Organ & Tissue Procurement Organization	3	X	X	•	•
Lifebanc	5	X	X	•	•
LifeSource, Upper Midwest OPO	7	X	X	•	•
Midwest Organ Bank	6	X	X	•	•
Oklahoma Organ Sharing Network	4	X	X	•	•
Organ Procurement Agency of Michigan	10	X	X	•	•
LifeGift Organ Donation Center ^d	7	•	X	X	M, O
LifeNet	3	•	X	X	•
New Jersey Organ and Tissue Network	3	•	X	X	•
Southwest Organ Bank ^d	6	•	X	X	L, M, H
Tennessee Donor Services	5	•	X	X	•
New England Organ Bank	14	X	X	X	L, M, P

(Table notes on next page)

Appendix III
Variations in OPO Kidney Allocation

*One or both kidneys are allocated using a single list that includes all potential recipients listed with the OPO.

*One or both kidneys are allocated using a transplant center's list of recipients.

*One or both kidneys are allocated using a list of recipients from a group of transplant centers that are a subset of the OPO.

*Modifications do not apply to all transplant centers within the OPO.

Legend:

L=Increases weight given to patients on the list the longest.

M=Except for six-antigen matches, changes the weight given to HLA matching.

H=Changes the weight given to highly sensitized patients.

P=Changes the weight given to pediatric patients.

O=Changes other factor(s).

Source: Questionnaire responses and UNOS.

Reasons for Not Selecting Potential Recipients Under Consideration (Based on 419 Organ Placements)

Reason	Frequency	Percent of Total
Potential recipient had a positive crossmatch result (indicating likely rejection of the organ).	2087	42.64
Reason was not documented.	1220 ^a	24.93
Donor had certain medical, physical, or social characteristics.	451	9.22
Potential recipient was unavailable.	265	5.41
Potential recipient was skipped for some administrative reason. ^b	116	2.37
Surgeon was unavailable.	105	2.15
Potential recipient's antigens matched poorly with the donor's.	104	2.13
Transplant program was too busy.	92	1.88
Potential recipient received an organ from this donor (i.e., other kidney or lung).	91	1.86
Potential recipient was too ill for the surgery.	81	1.66
Organ was the wrong size.	74	1.51
Laboratory or test results indicated potential problems.	72	1.47
Potential recipient or physician refused the organ.	42	0.86
Potential recipient had previously received a transplant.	42	0.86
Organ was damaged or had another anatomical problem.	40	0.82
No blood culture was available to conduct tests.	11	0.22
Time organ was preserved on ice was viewed as too long.	1	0.02
Total Patients Skipped	4,894	100

^aFor the 10 OPOs, the number of patients skipped where the reason was not documented ranged from 4 at one OPO to 311 at another.

^bExamples of administrative reasons include the following: (1) a lack of transportation for the organ or patient and (2) patients who were still on the list even though their transplant program was no longer operational.

Variations in OPO Procurement in 1991

Organ procurement organization	Service area population	Transplant centers ^a	Hospitals ^b	Organ donors	Donors per million population	Organs	Organs per million population
Alabama Regional Organ and Tissue Center	4,236,799	2	67	99	23.37	275	64.91
Albany Medical College	2,140,126	1	45	33	15.42	103	48.13
Arizona Organ Bank	3,665,228	6	70	57	15.55	182	49.66
Arkansas Regional Organ Recovery Agency	1,373,105	3	93	34	24.76	112	81.57
California Transplant Donor Network	8,514,325	5	169	186	21.85	639	75.05
Carolina Organ Procurement Agency	3,294,203	3	56	54	16.39	190	57.68
Carolinas Medical Center	1,788,174	1	35	19	10.63	61	34.11
Central Texas Organ Program	974,949	2	13	22	22.57	84	86.16
Colorado Organ Recovery Systems	3,672,986	5	91	53	14.43	198	53.91
Delaware Valley Transplant Program	10,145,168	10	168	201	19.81	672	66.24
Froedtert Memorial Lutheran Hospital	2,169,463	4	38	51	23.51	181	83.43
Golden State Transplant Services	1,712,294	2	28	37	21.61	111	64.83
Hartford Hospital OPO	1,552,727	1	21	23	14.81	77	49.59
Hawaii Organ Procurement Organization	1,108,229	1	17	13	11.73	27	24.36
Hillcrest Health Care System OPO	1,179,180	1	14	10	8.48	31	26.29
Indiana Organ Procurement Organization	4,740,780	4	103	78	16.45	281	59.27
Intermountain Organ Recovery	2,169,595	4	84	57	26.27	194	89.42
Iowa Statewide Organ and Tissue Procurement Organization	2,559,890	3	117	45	17.58	161	62.89
Kentucky Organ Donor Affiliates	3,289,825	3	112	78	23.71	250	75.99
Life Connection of Ohio	2,472,522	2	51	46	18.60	141	57.03
Lifebanc	4,161,380	5	81	63	15.14	195	46.86
LifeGift Organ Donation Center	6,458,398	7	206	118	18.27	386	59.77
Lifeline of Ohio	2,642,740	2	62	72	27.24	280	105.95
LifeLink of Florida	2,541,773	2	54	81	31.87	268	105.44
LifeLink of Georgia	4,346,244	4	101	71	16.34	245	56.37
Lifelink of Southwest Florida	978,935	1	20	25	25.54	76	77.64
LifeNet Virginia Tissue Bank	2,737,059	5	42	59	21.56	184	67.23
Life Resources Regional Donor Center	635,668	1	22	19	29.89	53	83.38
LifeSource, Upper Midwest OPO	5,801,912	9	169	117	20.17	457	78.77
Louisiana Organ Procurement Agency	4,219,973	6	101	81	19.19	294	69.67
Medical College of Georgia	1,967,617	1	79	26	13.21		^c

(continued)

**Appendix V
Variations in OPO Procurement in 1991**

Organ procurement organization	Service area population	Transplant centers^a	Hospitals^b	Organ donors	Donors per million population	Organs	Organs per million population
Mid-America Transplant Association	4,126,873	5	127	80	19.39	226	64.46
Mid-South Transplant Foundation	1,294,449	4	29	26	20.09	94	72.62
Midwest Organ Bank	4,695,087	6	220	101	21.51	330	70.29
Nebraska Organ Retrieval System	1,561,643	4	22	45	28.82	172	110.14
Nevada Donor Organ Recovery	1,201,833	3	23	27	22.47	96	79.88
New England Organ Bank	11,618,371	14	196	174	14.98	556	47.86
New Jersey Organ and Tissue Network	5,987,846	4	72	73	12.19	211	35.24
New Mexico Donor Program	1,515,069	2	38	46	30.36	149	98.35
New York Regional Transplant Program	9,113,955	8	91	158	17.34	475	52.12
North Carolina Baptist Hospital	1,786,468	1	39	27	15.11	82	45.90
Northwest Kidney Center	5,081,913	4	139	84	16.53	381	74.97
Ohio Valley Procurement Center	1,839,876	3	30	38	20.65	138	75.01
Oklahoma Organ Sharing Network	1,932,577	4	72	31	16.04	104	53.81
Organ and Tissue Acquisition Center	2,607,319	3	26	71	27.23	232	88.98
Organ Procurement Agency of Michigan	9,295,297	10	128	175	18.83	528	56.80
Pacific Northwest Transplant Bank	3,551,900	1	20	69	19.43	229	64.47
Pittsburgh Transplant Foundation	4,419,803	5	98	96	21.72	317	71.72
Puerto Rico Transplant Office	3,623,846	1	5	3	0.83	6	1.66
Regional Organ Bank of Illinois	11,126,309	9	181	179	16.09	583	52.40
Regional Organ Procurement Agency of Southern California	12,312,344	15	146	156	12.67	458	37.20
Sacred Heart Medical Center	956,480	2	39	23	24.05	83	86.78
Southern California Organ Procurement and Preservation Center	3,563,941	3	61	96	26.94	312	87.54
South Carolina Organ Procurement Agency	3,215,891	1	68	46	14.30	155	48.20
South Texas Organ Bank	2,849,071	3	58	39	13.69	134	47.03
Southwest Organ Bank	6,625,361	8	208	146	22.04	481	72.60
Stony Brook Transplantation Services	2,609,212	1	29	18	6.90	40	15.33
Tennessee Donor Services	3,605,727	5	107	62	17.19	225	62.40
Translife, East Central Florida Transplant Program	2,114,377	1	33	61	28.85	194	91.75
Transplant Resource Center of Maryland	2,921,092	3	35	62	21.22	205	70.18
University of Florida	2,700,606	3	86	56	20.74	211	78.13
University of Miami OPO	4,570,658	2	80	88	19.25	229	50.10

(continued)

Appendix V
Variations in OPO Procurement in 1991

Organ procurement organization	Service area population	Transplant centers ^a	Hospitals ^b	Organ donors	Donors per million population	Organs	Organs per million population
University of Mississippi Medical Center	2,505,306	1	74	22	8.78	68	27.14
University of Rochester Medical Center	2,363,371	2	47	46	19.46	168	71.08
University of Wisconsin Hospital	2,630,297	3	52	78	29.65	270	102.65
Upstate New York Transplant Services	1,568,454	4	36	23	14.66	58	36.98
Virginia Organ Procurement Agency	1,525,655	2	52	29	19.01	129	84.55
Washington Regional Transplant Consortium	3,923,574	8	41	68	17.33	210	53.52
Total	248,193,118	264	5,137	4,550	*	14,987	*
Mean	3,649,899	4	76	67	19.15	224	64.20
Median	2,718,833	3	62	57	19.00	194	64.00

^aNumber of transplant centers (both inside and outside the OPO's service area) that listed patients with the OPO.

^bNumber of hospitals (both inside and outside the OPO's service area) that referred or agreed to refer potential donors to the OPO.

*OPO did not provide data on number of organs procured for 1991.

Source: UNOS provided the service area populations for each OPO as reported to UNOS by HCFA. Other information was provided by the questionnaire responses.

Status of Required Request and Routine Inquiry Laws

In hopes of increasing organ procurement, most states and the federal government have implemented legislation, known as required-request laws, to insure families are offered the opportunity to donate. In its 1986 report,¹ the congressionally mandated Task Force on Organ Transplantation concluded that many opportunities for organ donation were being lost because families were not aware of their option to donate or failed to remember this option in their time of grief. The report recommended that policies be adopted by all hospitals, states, and the federal government to assure that the family is offered the opportunity to donate.

Federal and State Laws

The Congress and most states have enacted some type of required request legislation. This legislation falls into two general categories: (1) required request, which actually mandates that a request for donation be made and (2) routine inquiry, which only requires that the next-of-kin be made aware of the option or opportunity to donate.

The federal law, enacted as part of the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509, Section 9318(a)), is a routine inquiry law. It requires all hospitals participating in Medicare and Medicaid to establish written protocols regarding organ donation. In order to be in full compliance with the federal law, hospitals must have policies and procedures to (1) identify potential organ donors, (2) refer potential donors to OPOs, and (3) assure that families of potential organ donors are made aware of the option of organ donation and their option to decline to donate. Additionally, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations² must also have documentation that families have been given the option to donate organs and that potential donors have been referred to organ procurement organizations (OPOs).

As of 1988, 43 states and the District of Columbia had required request and routine inquiry laws.³ We contacted officials in the remaining seven states and found that five of these states had since enacted similar laws.

¹Organ Transplantation, Issues and Recommendations, Report of the Task Force on Organ Transplantation, Task Force on Organ Transplantation, U.S. Department of Health and Human Services (Washington, D.C.: 1986).

²Section 1865 of the Social Security Act requires JICFA to accept Joint Commission accreditation of a hospital as evidence that it meets the Medicare definition of a hospital.

³Evaluation of Methods Used by States to Expand the Number of Organ and Tissue Donors, Maximus, Inc. (Falls Church, Va.: 1988).

Compliance Is Uncertain

Compliance with required request and routine inquiry laws is uncertain. Six of the ten OPOs that GAO visited stated they believed hospitals were not complying with either the federal or state laws. In addition, one of the recommendations from the Surgeon General's Workshop on Increasing Organ Donation was that hospital compliance be improved.⁴

Some experts have found evidence that more hospitals are beginning to comply with these laws.⁵ Preliminary results from an ongoing study of donation practices at 22 hospitals in two metropolitan areas over 2 years, suggest that the families of most eligible donors are asked to donate.⁶

Results of 1991 monitoring efforts also indicate that hospitals may be complying with the federal routine inquiry law. Monitoring is divided between the Joint Commission, which surveys most of the hospitals, and HCFA. In 1991, approximately 90 percent of the 1,761 hospitals surveyed by the Joint Commission and, according to a HCFA official, the hospitals surveyed by state survey agencies under contract with HCFA were in compliance with the federal routine inquiry law.

Impact of Required Request/Routine Inquiry

While GAO's survey of the 68 OPOs showed that OPOs believe that federal and state required request and routine inquiry legislation currently helps slightly more than it hinders procurement, it is currently impossible to assess the impact of such legislation. As shown in table VI.1, a majority of the OPOs stated that the federal law helps the OPOs in identifying donors but does not help the OPOs in obtaining consent for organ donation.

Table VI.1: OPOs' Opinions on the Effectiveness of the Federal Routine Inquiry Law on Organ Procurement Activities

Procurement activity	Greatly or somewhat helps	Neither helps nor hinders	Greatly or somewhat hinders
Identifying potential organ donors	43	20	5
Obtaining consent for organ donation	14	34	20

⁴The Surgeon General's Workshop on Increasing Organ Donation: Proceedings, U.S. Department of Health and Human Services (Washington, D.C.: 1991).

⁵A. Caplan, L. Siminoff, R. Arnold, and B. Virnig, "Increasing Organ and Tissue Donation: What Are the Obstacles, What Are Our Options?" The Surgeon General's Workshop on Increasing Organ Donation: Background Papers, U.S. Department of Health and Human Services, (Washington, D.C.: 1991), pp. 109-232.

⁶Beth A. Virnig and Arthur L. Caplan, "Required Request: What Difference Has It Made?" Transplant Proceedings, Vol. 24, No. 5 (1992), pp. 2155-58.

Thirty of the 68 OPOs stated that their state laws at least somewhat help in their OPO's ability to procure organs while 23 OPOs stated that their state laws neither help nor hinder the OPO and 16 stated their state laws somewhat hinder the OPO.⁷ The majority of the 10 OPOs we visited stated that positive effects of the federal and state laws include increased cooperation between hospital and OPO staff and increased likelihood of hospitals allowing the OPO to educate the hospital staff on identifying potential donors and approaching families.

The specific impact of required request and routine inquiry legislation on increasing procurement has been difficult to determine due to a variety of factors. While procurement has increased moderately since the laws were passed, it is difficult to attribute this increase to the legislation since a number of other factors are involved. For example, the recent increase in procurement may be due to expanding the minimum criteria for organ donor acceptance. Many OPOs, according to UNOS officials, have expanded their maximum age criteria from 60 years old to include donors up to age 70 or 75. Additionally, any changes in the size of the potential donor pool are unknown. Contributing to an increase in the donor pool is the increase in the U.S. population in general and contributing to its decline are the rise of AIDS and laws aimed at decreasing the incidence of accidental deaths, such as seat belt and motorcycle helmet laws.

Required request and routine inquiry laws were also intended to give families the opportunity to consider donation. These laws may have resulted in a larger percentage of families being asked to donate organs, but there is little information on the annual number of potential donors or on the number of families who have been given the option to donate organs. According to GAO questionnaire results, at least 7,117 families were given the option to donate the organs of a deceased relative in 1991.

⁷Some OPOs serve transplant centers or donor hospitals in more than one state.

Alternatives for Meeting the Demand for Organ Transplantation

As the demand for human organs continues to outpace the number of organs donated, health policy specialists are examining alternative methods for meeting the demand for organ transplantation. Many of these alternatives are controversial and raise various ethical issues. These options can be categorized into two groups (1) policy alternatives and (2) procedural alternatives. Described below are some of the policy and procedural alternatives currently being considered.

Policy Alternatives

The implementation of the following policy alternatives generally require that current laws governing organ donation be modified.

Required Referral

Some experts such as those at the Surgeon General's Workshop on Increasing Organ Donation have recommended that required referral be implemented. Such a policy would require hospitals to notify an OPO of all deaths. Advocates state this policy would increase donation because all potential donors would be referred to an OPO and no potential donors would be overlooked by a hospital. Officials at 8 of the 10 OPOs we visited stated that they believed required referral would at least somewhat increase the number of actual organ donors.

Before required referral can be implemented, various issues about its feasibility must first be settled. For example, according to one OPO official, OPOs, especially those that do not handle tissue donation, may lack the resources to manage required referral for all deaths. In addition, according to another OPO official, hospitals may feel that required referral would be a burden for them.

Financial Incentives for Donation

One suggestion for increasing organ donation is to offer financial incentives to donor families. Currently federal law prohibits the purchase of donor organs; however, some health policy specialists have been examining the option of paying the families of organ donors who, by donating, enable others to live. This compensation could take various forms such as assistance with funeral expenses, cash to the donor's estate, or a cash contribution to a charity chosen by the donor or the donor's family.

While some experts believe incentives are needed to encourage families to consent to organ donation, others believe incentives could actually decrease organ donation. Fifty-two percent of the respondents in a

national survey of the public stated that some form of compensation should be offered in an effort to increase the number of organs for donation; however, survey responses may not accurately predict public reaction if the proposed incentives were actually enacted.¹ For example, financial incentives may conflict with the beliefs of major religious organizations in this country. In contrast, some experts believe incentives might decrease organ donation by offending the public, undermining the current altruistic motivation which may be essential to the organ donation system. Officials at 6 of the 10 OPOs we visited believed financial incentives would decrease the number of organ donors, while officials at 2 OPOs believed incentives for organ donation would increase the number of organ donors. Officials at the other 2 OPOs were uncertain about the effect of financial incentives.

Presumed (Implied) Consent

Some experts believe that presumed or implied consent legislation might increase the number of organ donors. Currently, all organs for transplantation donated in the U.S. are obtained after explicit consent has been given by the family of the deceased person. On the other hand, presumed consent legislation, if enacted would assume consent is given unless the family or donor has specified otherwise. In several European countries, implied consent is currently practiced. The most successful experience with implied consent has been in Belgium where, during the first two years of the policy, a 117 percent increase in organ recovery was reported.

Arguments against the implementation of presumed consent have been mainly ethical. There is concern that this approach would hinder free choice by an individual because those with objections would have to state them prior to death in order to have their wishes abided by. In addition, according to one OPO official, it may be difficult to implement because many health care professionals may still be reluctant to take organs without routinely asking the family about their willingness to donate. When asked if "doctors in the U.S. should be able to act on presumed consent," 52 percent of respondents to a UNOS-sponsored national survey on public attitudes said no, 39 percent said yes, and 8 percent were undecided.² Officials at 5 of the 10 OPOs we visited stated that they believed presumed consent would decrease the number of organ donors.

¹Dilip S. Kittur, and others, "Incentives for Organ Donation?" *The Lancet*, Vol. 338 (1991), pp. 1441-43.

²Kittur and others, pp. 1441-43.

Procedural Alternatives

The implementation of the following procedural alternatives requires additional technological advancement and study as well as the elimination of other deterrents.

Expanding Donor Criteria

Many experts, including those attending the Surgeon General's Workshop on Increasing Organ Donation, have advocated increasing the number of donors by expanding the criteria for determining whether a donor is acceptable. For example, ORO and transplant center donor criteria could be expanded to include older donors and to selectively use systemically infected donors. Other experts may be reluctant to expand the donor criteria because it may put patients at greater risk of organ failure or some other negative side effect. Ongoing study is needed to ensure that the expanded donor criteria provides more overall benefit than risk.

Non-Heart-Beating Donors

Some experts argue that one way to significantly increase the potential donor pool is to recover organs from deceased patients whose hearts have stopped beating. Currently, only those patients pronounced brain dead and whose heart is kept beating through artificial assistance are generally considered for organ donation.³ Experts point out that it may not be necessary to limit procurement to those donors whose hearts are beating because deceased patients whose hearts are not beating can also be organ donors. In fact, non-heart-beating donors were used for kidney transplantation on a routine basis prior to the introduction of brain death legislation.

Perhaps the greatest concern in using non-heart-beating donors is a question about the quality of the organs. Additional testing may be necessary to determine the suitability of organs from non-heart-beating donors. Also, medical technology can extend organ viability by administering a preservative soon after death; however, there may not always be enough time to obtain consent from the family prior to administering the preservative.

Directed Donation

One suggestion for increasing organ donation is to promote directed donation where the organ donation is designated for a particular class or group of citizens. Currently, donor families are encouraged not to place any restrictions on the gift of their organs, even though the Uniform

³Some transplant centers in the United States, Europe, and Japan are retrieving and transplanting kidneys and livers from non-heart-beating donors.

Anatomical Gift Act, which has been adopted in most states, provides for donors to specify how organs may be used.

Advocates believe that directed donation might increase consent rates especially among minority groups. For example, a black donor family could be assured that their loved one's organs would in all likelihood be able to benefit another black person in need. Opponents argue that allocation should be impartial to race and other factors, that it is wrong to allocate an organ to someone other than the person who would have received the organ had the donation not been directed to another group.

Living Donors

One means of expanding the donor pool is expanding the use of living donors, individuals who are usually related biologically or emotionally to the organ recipient. In 1991, 2,216 living individuals donated an organ, usually a kidney, or part of an organ, such as a liver segment.

The use of living donors is hampered by ethical considerations as well as other obstacles. Ethically, the benefit to the recipient must be weighted carefully against the potential harm that living donation may impose upon the donor. In addition, individuals are deterred from being living donors due to a lack of compensation for time off work, fear of pain and disfigurement, and a lack of compensation in the event of a donation-related disability or death.

Xenografts

Animals may be another potential source of organs for transplantation. To date, few xenografts (transplants of animal organs into humans) have been performed; however, their feasibility is being researched.

Various ethical, psychological, and public policy issues surround xenografting. Ethically, the morality of killing animals for the sole purpose of using their organs for transplantation is questioned.⁴ Psychologically, potential recipients may have difficulty with the idea of receiving an animal organ. Procedurally, the use of animals is currently so experimental that some argue informed consent procedures must be especially rigorous and peer review exceedingly conscientious before any potential recipients can be recruited.

⁴A.L. Caplan, "Is Xenografting Morally Wrong?" *Transplantation Proceedings*, Vol. 24, No. 2 (1992), pp. 722-27.

Artificial Organs

Artificial organs, or mechanical devices, are another alternative for patients suffering organ failure. The artificial kidney, or renal dialysis, already provides safe and effective treatment for many of the conditions that cause irreversible kidney failure. Some heart assistance devices, such as pacemakers, are now routinely used in treatment; however, the implantable artificial heart remains an experimental medical device, which affords patients neither the safety nor the quality of life that kidney dialysis does. Technological improvements are needed if other artificial organs are to move beyond experimental to routine therapy.

HHS Letter Stating Their Position on Arrangements Between Hospitals and OPOs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

APR 10 1992

Associate Administrator for
Program Development
Washington, D.C. 20201

Mr. Barry R. Bedrick
Associate General Counsel
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Bedrick:

I am responding to your letter to Secretary Sullivan concerning arrangements made by hospitals to deal with organ procurement organizations (OPOs).

At the time we issued the OPO regulations, we indicated that while the law required us to designate only one OPO per service area, the regulations would give hospitals flexibility to have arrangements with any designated OPO. We did this because transplant centers expressed concern about disrupting their longstanding, satisfactory relationships with OPOs. We developed this policy after consulting with representatives of the hospital and OPO communities. Since the intent of the law was to reduce confusion over organ procurement and to increase organ retrieval, our goal was to eliminate duplication of organ procurement efforts and at the same time to minimize unnecessary disruption of already existing hospital/OPO relationships. We note that the law (section 1138(a)(1)(A)(iii) of the Social Security Act, 42 U.S.C. § 1320b-8(a)(1)(A)(iii)) requires hospitals to notify "an organ procurement agency designated by the Secretary" (emphasis added). It does not require that a hospital notify the OPO designated for its geographic area.

In addition, section 371(b)(3)(A) of the Public Health Service Act, 42 U.S.C. § 273(b)(3)(A), requires organ procurement organizations to have "effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations." By its terms, it does not require OPOs to have agreements with all organ-donating hospitals in its area, and thus affords OPOs and hospitals the flexibility to have extra-service area arrangements without undermining an effective OPO's ability to operate.

The OPO regulations have been in effect for several years. The Association of Organ Procurement Organizations estimates that about half of the designated OPOs have arrangements with at least one hospital outside their service area. We are not convinced that we should eliminate the flexibility that now exists between hospitals and OPOs by changing the regulations at this time.

Appendix VIII
HHS Letter Stating Their Position on
Arrangements Between Hospitals and OPOs

Page 2 - Mr. Barry R. Bedrick

However, we will be publishing a final rule with comment on "Conditions of Coverage for Organ Procurement Organizations." (The notice of proposed rulemaking was published in the Federal Register on June 21, 1991.) Because we received a few comments on this issue, we currently to solicit comments on whether we should require hospitals to work only with the designated OPO for their area.

I hope this information explains our position on this particular issue. If I can be of further assistance, please let me know.

Sincerely,

A handwritten signature in dark ink, appearing to read "Robert G. Eaton". The signature is fluid and cursive, with the first name "Robert" being more prominent.

Robert G. Eaton
Associate Administrator
for Program Development

Data Supporting Figures in Report

Table IX.1: Data for Figure 1.1

Year	Organs needed: annual number of people on the waiting list	Donated organs obtained for transplantation
1988	30,090	12,006
1989	34,370	12,731
1990	39,885	14,899
1991	44,295	15,503
1992	49,933	15,715

Table IX.2: Data for Figure 3.1

Stages in the procurement process	Number of potential and actual donors
Referral to OPO	10,341
Consent requested	6,983
Consent obtained	4,158
Donation	3,396

U.S. General Accounting Office Survey of Organ Procurement Organizations' Procurement and Allocation Practices

U.S. GENERAL ACCOUNTING OFFICE
Survey of Organ Procurement Organizations' Procurement and Allocation Practices

INTRODUCTION

The U.S. General Accounting Office (GAO) is conducting an evaluation required under the Transplant Amendments Act of 1990 (P.L. 101-616). This law requires that GAO evaluate certain aspects of organ procurement and allocation.

As part of our evaluation of all organ procurement organizations (OPOs), we are gathering information about procurement and allocation activities in general and your OPO's policies and procedures in particular. Although this questionnaire may appear lengthy, most of the questions can be completed by checking boxes. A few questions, however, may require a little additional time so that you can consult your OPO's records.

INSTRUCTIONS

We realize that terms may be defined differently by each OPO. For the purposes of this study, please use the following definitions:

- A potential organ donor is a patient on a ventilator, with brain death present or imminent, who may or may not meet your OPO's organ donor acceptance criteria.
- An organ donor is a brain dead patient from whom your OPO procured one or more organs for the purposes of transplantation.

This questionnaire should be completed by the person most familiar with your OPO procurement and allocation activities. Please give the name, title, and telephone number of the person mainly responsible for completing the questionnaire so that we may consult him or her, if necessary, for clarification or additional information.

Name of person: _____

Official title: _____

Telephone number: () _____

If you have any questions, call Susan Spitzer, Tim Fairbanks, or Howard Cott collect at (213) 346-8000. Please return the completed questionnaire within 2 weeks of receipt. In the event the envelope is misplaced, please send your questionnaire to

Ms. Susan Spitzer
U.S. General Accounting Office
Los Angeles World Trade Center
350 S. Figueroa Street, Suite 1010
Los Angeles, CA 90071

If you would like to fax your responses, our number is (213) 346-8142.

Thank you for your help.

Note: This questionnaire was sent to the 68 OPOs which, at the time, were designated by HCFA. All OPOs returned the questionnaire, however some did not respond to all questions. For questions showing median and range of responses, the "N" denotes the number of OPOs responding to that question.

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

BACKGROUND

According to Health Care Financing Administration (HCFA) records, your service area includes

Note: Here we inserted each OPO's HCFA-designated service area, as provided by HCFA.

Please answer the following questions in reference to the above HCFA-designated service area.

1. In what year was your OPO established? (Enter year) (N=68)

<u>Range</u>	<u>Median</u> ¹
1966-1989	1979

2. In what year was your OPO designated by the Secretary of the U.S. Department of Health and Human Services as the only OPO for its service area, that is, the geographic area it serves? (Enter year) (N=68)

<u>Range</u>	<u>Median</u>
1975-1990	1987

¹Median is the value at which 50 percent of the responses fall above and 50 percent fall below.

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

3. Now we would like you to consider all hospitals located in your HCFA-designated service area in 1991. Please enter the requested information in Parts A, B, and C for each type of hospital listed below:

Part A: Enter the number of hospitals located in your HCFA-designated service area, regardless of whether or not your OPO served each hospital, in 1991. (If none, enter "0")

Part B: Enter the number of hospitals located in your HCFA-designated service area, during 1991, that referred potential organ donors to your OPO or had an agreement to refer them. (If none, enter "0")

Part C: Enter the number of hospitals located in your HCFA-designated service area, during 1991, that referred potential organ donors to another OPO or had an agreement to refer them. (If none, enter "0")

Hospital type	PART A Number of hospitals located in HCFA-designated service area in 1991	PART B Number of hospitals in HCFA-designated service area that referred, or agreed to refer, potential organ donors <u>to your OPO</u> during 1991	PART C Number of hospitals in HCFA-designated service area that referred, or agreed to refer, potential organ donors <u>to another OPO</u> during 1991
1. Acute care hospital with trauma center (Level 1 facility that has the capability to provide care for every aspect of physical injury)	(N=68) <u>Range</u> 0-39 <u>Median</u> 3	(N=68) <u>Range</u> 0-39 <u>Median</u> 3	(N=66) <u>Range</u> 0-5 <u>Median</u> 0
2. Acute care hospital with no Level 1 trauma center, but with an emergency room	(N=67) <u>Range</u> 10-225 <u>Median</u> 50	(N=68) <u>Range</u> 4-197 <u>Median</u> 45	(N=66) <u>Range</u> 0-27 <u>Median</u> 0
3. Acute care hospital with no emergency room or trauma center	(N=62) <u>Range</u> 0-56 <u>Median</u> 3	(N=62) <u>Range</u> 0-54 <u>Median</u> 1	(N=62) <u>Range</u> 0-4 <u>Median</u> 0
4. Other (such as, rehabilitation hospital, psychiatric hospital, etc.)	(N=60) <u>Range</u> 0-54 <u>Median</u> 5	(N=59) <u>Range</u> 0-34 <u>Median</u> 1	(N=61) <u>Range</u> <u>Median</u> 0
TOTAL	(N=68) <u>Range</u> 4-275 <u>Median</u> 80	(N=68) <u>Range</u> 5-220 <u>Median</u> 57	(N=65) <u>Range</u> 0-31 <u>Median</u> 0

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

4. During 1991, did your OPO obtain potential donor referrals from, or have an agreement with, hospitals outside your HCFA-designated service area?

1. [32] Yes --> How many hospitals? (Enter number) Range Median (N=32)
1-49 2

2. [36] No

5. Listed below are various types of hospitals.

Part A: Enter the number of donors from which organs were procured by your OPO, during 1991, from each type of hospital in your HCFA-designated service area. (Enter number; If none, enter "0")

Part B: Enter the number of donors from which organs were procured by your OPO, during 1991, from each type of hospital outside your HCFA-designated service area. (Enter number; If none, enter "0")

Hospital type	PART A Number of donors from which organs were procured from each type of hospital in your HCFA- designated service area during 1991	PART B Number of donors from which organs were procured from each type of hospital <u>outside</u> your HCFA-designated service area during 1991
1. Acute care hospital with trauma center (Level 1 facility that has the capability to provide care for every aspect of physical injury)	(N=66) <u>Range</u> <u>Median</u> 0-131 26	(N=68) <u>Range</u> <u>Median</u> 0-16 0
2. Acute care hospital with no Level 1 trauma center, but with an emergency room	(N=67) <u>Range</u> <u>Median</u> 0-102 23	(N=67) <u>Range</u> <u>Median</u> 0-43 0
3. Acute care hospital with no emergency room or trauma center	(N=66) <u>Range</u> <u>Median</u> 0-2 0	(N=66) <u>Range</u> <u>Median</u> 0 0
4. Other (such as, rehabilitation hospital, psychiatric hospital, etc.)	(N=67) <u>Range</u> <u>Median</u> 0 0	(N=66) <u>Range</u> <u>Median</u> 0 0
TOTAL	(N=68) <u>Range</u> <u>Median</u> 3-201 55	(N=68) <u>Range</u> <u>Median</u> 0-59 0

6. As of December 31, 1991, how many transplant centers, that is hospitals that have a transplant program, were located within your HCFA-designated service area? If none, check the box below. (Enter number) (N=68)

Range Median
1-14 3 transplant centers

00. [] No transplant centers --> (Go to question 8)

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

7. Of the transplant centers located within your HCFA-designated service area as of December 31, 1991, how many (1) listed their patients with your OPO and (2) did not list their patients with your OPO? (Enter number; If none, enter "0")

Range Median
 (1) 1-14 3 transplant centers within that listed patients with your OPO (N=68)
 (2) 0-4 0 transplant centers within that listed patients with another OPO (N=67)

8. Again, as of December 31, 1991, how many transplant centers located outside your HCFA-designated service area listed their patients with your OPO? (Enter number; If none, enter "0")

Range Median
0-3 0 transplant centers outside that listed patients with OPO (N=66)

9. For each organ listed below, enter the number of transplant centers that listed their patients with your OPO as of December 31, 1991, (1) within your HCFA designated service area and (2) outside your HCFA designated service area . (Enter number; If none, enter "0")

Organ	(1) Number of transplant centers within HCFA service area			(2) Number of transplant centers outside HCFA service area		
		<u>Range</u>	<u>Median</u>		<u>Range</u>	<u>Median</u>
1. Kidney	(N=68)	<u>1-14</u>	<u>2</u>	(N=68)	<u>0-3</u>	<u>0</u>
2. Heart	(N=67)	<u>0-6</u>	<u>2</u>	(N=66)	<u>0-2</u>	<u>0</u>
3. Liver	(N=67)	<u>0-6</u>	<u>1</u>	(N=67)	<u>0-1</u>	<u>0</u>
4. Pancreas	(N=67)	<u>0-4</u>	<u>1</u>	(N=67)	<u>0-1</u>	<u>0</u>
5. Lung	(N=67)	<u>0-4</u>	<u>1</u>	(N=67)	<u>0-1</u>	<u>0</u>
6. Heart/lung	(N=67)	<u>0-5</u>	<u>1</u>	(N=67)	<u>0-1</u>	<u>0</u>

10. Listed below are various sources that might have referred potential organ donors to your OPO during 1991. About what percentage of total referrals did each of these sources--donor hospitals, transplant centers, and others--make to your OPO? (Enter percentage)

Source of referral	Percentage of total referrals	
1. Donor hospital	<u>Range</u> (N=66)	<u>Median</u> 100%
2. Transplant center (that is, when the center is not also the donor hospital)	<u>Range</u> (N=66)	<u>Median</u> 0%
3. Other (Specify) _____	<u>Range</u> (N=64)	<u>Median</u> 0%
100 %		

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

11. Listed below is information your OPO may have collected on potential organ donors referred to your OPO during 1991. Did your OPO usually collect information indicating

(Check one for each statement)

	<u>Yes</u>	<u>No</u>
1. who first initiated the subject of organ donation with the family?	[40]	[28]
2. whether or not consent was requested?	[64]	[4]
3. the reason(s) consent was not requested?	[58]	[9]
4. who requested consent for organ donation?	[55]	[13]
5. whether the request was made at the same time that brain death was explained to the family?	[20]	[48]
6. whether the request was made in a separate discussion sometime after brain death had been explained to the family?	[21]	[47]
7. whether consent was given or denied?	[67]	[1]
8. the reason(s) that consent was denied?	[49]	[19]
9. the race or ethnicity of the potential organ donor?	[62]	[6]

12. For calendar years 1990 and 1991, please indicate the total number of.....

	<u>1990</u>	<u>1991</u>
1. potential organ donors referred to your OPO	(N=63) Range 20-623 Median 143	(N=64) 19-742 153
2. potential organ donors for whom consent was requested	(N=52) Range 12-404 Median 110	(N=54) 12-420 98
3. potential organ donors for whom consent was obtained	(N=57) Range 3-264 Median 59	(N=60) 3-321 62
4. organ donors	(N=67) Range 4-227 Median 55	(N=68) 3-201 57

13. For each organ type listed below, please provide the total number of organs procured for transplantation by your OPO in 1990 and 1991. (Enter number for each year)

	<u>1990</u>	<u>1991</u>
1. Kidney (N=67)	Range 8-426 Median 102	6-384 104
2. Heart (N=66)	Range 3-101 Median 26	3-95 28
3. Liver (N=66)	Range 0-158 Median 36	1-162 40
4. Lung (N=66)	Range 0-20 Median 2	0-26 5
5. Pancreas (N=66)	Range 0-44 Median 6	0-66 7
6. Heart/lung ²	(N=10) Range 0-10 Median 2	(N=12) 0-8 2

²Question 13, response item 6 was not part of the GAO questionnaire; however, some OPOs wrote in this item.

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

14. Consider all the potential organ donors that were referred to your OPO during 1991. For about what percentage of these referrals, was your OPO staff the first to initiate the subject of organ donation with the family? (Check one)

1. [1] 81-100 %

2. [1] 61-80 %

3. [9] 41-60 %

4. [13] 21-40 %

5. [28] 1-20 %

6. [10] 0 %

7. [6] Don't know

15. For about what percentage of the organ donor referrals during 1991, did your OPO staff ask the potential organ donor's family for consent for organ donation? (Check one)

1. [16] 81-100 %

2. [12] 61-80 %

3. [18] 41-60 %

4. [10] 21-40 %

5. [9] 1-20 %

6. [0] 0 %

7. [3] Don't know

16. Does your OPO have racial or ethnic minority staff to discuss organ donation with a minority family? (Check one)

1. [21] Yes

2. [47] No

17. Does your OPO train its staff who request consent for organ donation in how to approach racial or ethnic minority families for organ donation? (Check one)

1. [47] Yes

2. [21] No

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

ACCEPTANCE CRITERIA FOR ORGAN DONORS

18. Now we would like to ask you about the criteria your OPO uses to accept organ donors.

Does your OPO have either age or disease criteria to determine if brain dead patients are acceptable or unacceptable organ donors? (Check one)

1. [67] Yes
2. [1] No criteria --> (Go to question 23)

19. Between what ages are referred donors considered acceptable potential organ donors? If your OPO does not have an age criteria, check the box below. (Enter number for each)

- | | <u>Range</u> | <u>Median</u> | |
|--------------------------|------------------|----------------|--------|
| 1. Minimum age | <u>Newborn-2</u> | <u>Newborn</u> | (N=58) |
| 2. Maximum age | <u>60-90</u> | <u>70</u> | (N=57) |
| 00. [9] No age criteria | | | |

20. Indicate whether or not your OPO would accept as an organ donor those who had each of the diseases listed below. If your OPO has no disease criteria, check box below. (Check one for each disease)

<u>Disease</u>	<u>Accept</u>	<u>Not Accept</u>
1. Hepatitis C	[44]	[22]
2. Primary brain tumor	[66]	[0]
3. Cancer other than a primary brain tumor	[13]	[53]
4. Other (Please specify)		
_____	[6]	[15]

00. [1] No disease criteria

21. Are you aware of the acceptance criteria for organ donors for all OPOs, most OPOs, about half of the OPOs, some of the OPOs, or few of the 68 OPOs, if any? (Check one)

1. [11] All, or almost all
2. [23] Most
3. [5] About half
4. [18] Some
5. [9] Few, if any

22. If another OPO refused a potential donor because its donor acceptance criteria were more restrictive than yours, would your OPO like to be called about that potential donor? (Check one)

1. [56] Yes
2. [11] No

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

ASSESSING YOUR OPO'S EFFORTS TO IDENTIFY OR REFER DONORS

23. Has your OPO ever attempted to assess hospitals' efforts to identify or refer potential organ donors? (Check one)

1. [65] Yes
2. [3] No --> (Go to question 26)

24. Did your OPO ever conduct a medical records review of patients who have died? (Check one)

1. [60] Yes
2. [5] No --> (Go to question 26)

25. Please indicate whether or not your medical records review included the following: (Check one for each statement)

	<u>Yes</u>	<u>No</u>	<u>Don't know</u>
1. Hospital compliance with federal-required request/routine inquiry law [54]	[5]	[1]	
2. Hospital compliance with state-required request/routine inquiry law(s) [53]	[6]	[1]	
3. Hospital identification of potential organ donors [60]	[0]	[0]	
4. Hospital referral of potential organ donors to your OPO [60]	[0]	[0]	
5. Consent rates for hospital staff requesters [38]	[20]	[2]	
6. Consent rates by racial or ethnic minorities [32]	[26]	[1]	
7. Other (Please specify) _____ [10]	[1]	[0]	

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

REQUIRED REQUEST/ROUTINE INQUIRY LAW

26. In your opinion, does the federal required request/routine inquiry law currently help or hinder your OPO in (1) identifying potential organ donors and (2) obtaining consent for organ donation? (Check one for each)

	Greatly helps	Somewhat helps	Neither helps nor hinders	Somewhat hinders	Greatly hinders	Don't know
1. Identifying potential organ donors	2	41	20	5	0	0
2. Obtaining consent for organ donation	0	14	34	18	2	0

27. For each state in which your OPO serves transplant centers or donor hospitals, in general, does the state required request/routine inquiry law currently help or hinder your OPO's ability to procure organs? (Please list state name. If the state does not have this law, check "not applicable.") (N=68)

State	Greatly helps	Somewhat helps	Neither helps nor hinders	Somewhat hinders	Greatly hinders	Not applicable
1. Total OPO responses ³	1	42	40	23	0	4
2.						
3.						
4.						
5.						
6.						

³Some OPOs serve transplant centers or donor hospitals in more than one state.

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

ALLOCATING ORGANS TO RECIPIENTS

Kidney Allocation

28. Now we would like to ask you several questions about the policies your OPO has had for allocating organs to recipients listed with your OPO.

Consider your OPO's policy for allocating kidneys--during calendar years 1989, 1990, and 1991--once allocation requirements were met for 6 antigen-matches, paybacks, or regional high PRA recipients. For each policy listed below, indicate whether or not your OPO had the policy during calendar years 1989, 1990, and 1991: (For each policy, check "yes" or "no" in each calendar year column.)

Policy	N=68		N=68		N=68	
	Calendar year 1989		Calendar year 1990		Calendar year 1991	
	Yes	No	Yes	No	Yes	No
1. Both kidneys are first allocated using a single list that includes all potential recipients listed with your OPO as well as all potential recipients listed at one or more other OPOs (for example, all potential recipients in the entire state).	1	65	2	65	7	60
2. Both kidneys are first allocated using a single list of all potential recipients listed with your OPO.	49	19	53	15	55	13
3. Both kidneys are first allocated using a transplant center's list of recipients from that transplant center alone. If a kidney cannot be allocated at this transplant center, other transplant centers' lists are considered.	7	60	6	61	6	61
4. Both kidneys are first allocated using a list of recipients from a group of transplant centers that are a subset of the OPO.	6	61	5	61	5	61
5. First kidney is allocated using a transplant center's list and the second kidney is allocated using a single OPO list of all potential recipients.	4	63	5	62	8	59
6. First kidney is allocated using a transplant center's list, and the second kidney is allocated using a single list of all potential recipients of the other transplant centers.	5	62	5	62	2	64
7. Other (Specify)						
	10	27	8	27	8	27

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

29. During 1991, was it your OPO's policy to allocate the donor's kidneys using a single list of either all potential recipients listed with your OPO or all potential recipients listed with your OPO as well as potential recipients listed with other OPOs? (Check one)

1. [48] Yes --> (Go to question 31)

2. [20] No

30. Which of the following describes your OPO's policy, during 1991, for selecting a transplant center's list of patients when allocating kidneys? (Check all that apply) N=19

1. [8] Priority was given to a transplant center when the donor was located at one of its assigned donor hospitals.

2. [16] Priority was given to a transplant center when an organ donor was located at that same transplant center.

3. [8] Priority was rotated among transplant centers and their patients.

4. [0] Priority was given to the transplant center(s) with the most patients on the waiting list(s).

5. [1] Priority was given to transplant center(s) for kidney/pancreas transplants until the quota was (were) met.

6. [2] Other (Please specify) _____

31. During 1991, was it your OPO's policy, once the allocation requirements for a 6 antigen-match or payback kidney were met, to consider all high panel reactive antibody (PRA) potential recipients located in your UNOS region? (Check one)

1. [21] Yes

2. [47] No

32. Is it your OPO's policy when allocating kidneys to use point values other than those in the standard UNOS point system? (Check one)

1. [13] Yes --> (Go to question 33)

2. [43] No --> (Go to question 34)

3. [7] Unable to determine because the transplant center allocates kidneys --> (Go to question 34)

4. [5] No, but we do use a system that prioritizes potential recipients differently than the UNOS point system⁴

⁴Question 32, response item 4 was not part of the GAO questionnaire; however, five OPOs indicated that this was their policy.

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

33. Please indicate what your OPO's policy is related to using point values. (Check all that apply) N=18

1. ☒ Alters the point system to increase the weight for those patients on the list the longest.
2. ☐ Except for six antigen matches, alters the point system to decrease or eliminate the weight given to HLA matching.
3. ☐ Alters the point system to increase the weight given to high PRA patients.
4. ☐ Alters the point system to decrease or eliminate the weight given to high PRA patients.
5. ☐ Alters the point system so that degree of medical urgency is considered.
6. ☐ Alters the point system to increase the weight given to patients needing a second transplant.
7. ☐ Alters the point system to increase the weight given to pediatric patients.
8. ☐ Alters the point system to decrease the weight given to pediatric patients.
9. ☐ Alters the point system so that recipient distance from organ donor is weighted.
10. ☐ Alters the point system to give weight to diabetic patients.
11. ☐ Alters the point system to weight crossmatch results instead of PRA.
12. ☐ Other (Please specify) _____

Heart Allocation

34. Since January 1, 1989, has your OPO served a heart transplant program? (Check one)

1. ☒ Yes
2. ☐ No --> (Go to question 40)

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

35. Indicate whether or not your OPO had each of the following policies for allocating hearts during calendar years 1989, 1990, and 1991: (For each policy, check "yes" or "no" in each calendar year column.)

Policy	N=61		N=61		N=61	
	Calendar year 1989		Calendar year 1990		Calendar year 1991	
	Yes	No	Yes	No	Yes	No
1. A heart is first allocated using a single list that includes all potential recipients listed with your OPO as well as all potential recipients listed at one or more other OPOs (for example, all potential recipients in the entire state).	7	51	11	47	15	44
2. A heart is first allocated using a single list of all potential recipients listed with your OPO.	48	11	47	12	48	11
3. A heart is first allocated using a transplant center's list of recipients from that transplant center alone. If a heart cannot be allocated at this transplant center, other transplant centers' lists are considered.	4	51	5	51	3	53
4. A heart is first allocated using a list of recipients from a group of transplant centers that are a subset of the OPO.	4	52	4	52	2	55
5. Other (Specify) _____	8	21	7	22	9	22

36. During 1991, was it your OPO's policy to allocate hearts using a single list of either all potential recipients listed with your OPO or all potential recipients listed with your OPO as well as potential recipients listed with other OPOs? (Check one)

1. [50] Yes --> (Go to question 38)
2. [17] No

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

37. Which of the following describes your OPO's policy, during 1991, for selecting a transplant center's list of patients when allocating hearts? (Check all that apply) N=11

1. ☐ [2] Priority was given to a transplant center when the donor was located at one of its assigned donor hospitals.
2. ☐ [8] Priority was given to a transplant center when an organ donor was located at that same transplant center.
3. ☐ [2] Priority was rotated among transplant centers and their patients.
4. ☐ [0] Priority was given to the transplant center(s) with the most patients on the waiting list(s).
5. ☐ [1] Other (Please specify) _____

38. Is it your OPO's policy when allocating hearts to use a priority system other than the standard UNOS system? (Check one)

1. ☐ [15] Yes --> (Go to question 39)
2. ☐ [43] No --> (Go to question 40)
3. ☐ [3] Unable to determine because the transplant center allocates hearts --> (Go to question 40)

39. Please indicate what your OPO's policy is related to using a priority system. (Check all that apply) N=15

1. ☐ [1] Alters the priority system to increase weight given to patients waiting the longest.
2. ☐ [0] Alters the priority system to decrease the weight given to medical urgency.
3. ☐ [0] Alters the priority system to decrease the weight given to distance from donor.
4. ☐ [6] Alters the priority system to increase the weight given to distance from donor.
5. ☐ [1] Alters the priority system to decrease the weight given to identical blood type over compatible blood type.
6. ☐ [17] Alters the priority system so that more than two medical urgency categories are used.
7. ☐ [2] Alters the priority system so that time waiting for Status I patients is calculated from the time the patient becomes a Status I patient.
8. ☐ [7] Other (Please specify) _____

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

Liver Allocation

40. Since January 1, 1989, has your OPO served a liver transplant program? (Check one)

1. [52] Yes

2. [16] No --> (Go to question 46)

41. Indicate whether or not your OPO had each of the following policies for allocating livers during calendar years 1989, 1990, and 1991: (For each policy, check "yes" or "no" in each calendar year column.)

Policy	N=52		N=52		N=52	
	Calendar year 1989		Calendar year 1990		Calendar year 1991	
	Yes	No	Yes	No	Yes	No
1. A liver is first allocated using a single list that includes all potential recipients listed with your OPO as well as all potential recipients listed at one or more other OPOs (for example, all potential recipients in the entire state).	5	44	7	42	10	40
2. A liver is first allocated using a single list of all potential recipients listed with your OPO.	39	11	40	10	41	10
3. A liver is first allocated using a transplant center's list of recipients from that transplant center alone. If a liver cannot be allocated at this transplant center, other transplant centers' lists are considered.	2	46	2	45	4	45
4. A liver is allocated using a list of recipients from a group of transplant centers that are a subset of the OPO.	1	47	0	47	1	47
5. Other (Specify)	7	18	4	19	3	21

42. During 1991, was it your OPO's policy to allocate livers using a single list of either all potential recipients listed with your OPO or all potential recipients listed with your OPO as well as potential recipients listed with other OPOs? (Check one)

1. [47] Yes --> (Go to question 44)

2. [4] No

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

43. Which of the following describes your OPO's policy, during 1991, for selecting a transplant center's list of patients when allocating livers? (Check all that apply) *N=4*

- 1. ☐ [1] Priority was given to a transplant center, when the donor was located at one of its assigned donor hospitals.
- 2. ☒ [4] Priority was given to a transplant center when an organ donor was located at that same transplant center.
- 3. ☐ [1] Priority was rotated among transplant centers and their patients.
- 4. ☒ [0] Priority was given to the transplant center(s) with the most patients on the waiting list.
- 5. ☒ [0] Other (Please specify) _____

44. Is it your OPO's policy when allocating livers to use point values other than those in the standard UNOS point system? (Check one)

- 1. ☐ [5] Yes --> (Go to question 45)
- 2. ☒ [44] No --> (Go to question 46)
- 3. ☐ [3] Unable to determine because the transplant center allocates livers --> (Go to question 46)

45. Please indicate what your OPO's policy is related to point values. (Check all that apply) *N=5*

- 1. ☒ [0] Alters the point system to increase the weight given to patients waiting the longest.
- 2. ☒ [0] Alters the point system to decrease the weight given to medical urgency.
- 3. ☐ [3] Alters the point system so that recipient distance from donor is weighted.
- 4. ☒ [0] Alters the point system to decrease the weight given to identical blood type.
- 5. ☐ [5] Other (Please specify) _____

OTHER INFORMATION

46. Please indicate which methods your OPO uses to obtain a list of potential recipients. (Check all that apply) *N=67*

- 1. ☒ [56] OPO accesses UNOS directly by OPO computer (that is, dialing through modem) to obtain list.
- 2. ☒ [46] OPO telephones UNOS to obtain the list.
- 3. ☐ [11] OPO generates its own list.
- 4. ☐ [3] Other (Please specify) _____

Appendix X
U.S. General Accounting Office Survey of
Organ Procurement Organizations'
Procurement and Allocation Practices

COMMENTS

47. If you have any comments about these questions, please write them in the space provided below.

24 OPOs wrote in comments.

44 OPOs did not write in comments.

Thank you for your help.

HRD/SLS/1-92

Rationale for Presenting Questionnaire Data

In some instances the OPO questionnaire responses reported in appendix X were combined and clarified to better present the responses to the reader. This appendix presents the methodology used when we combined and clarified the questionnaire responses.

Modifications to UNOS' Allocation Criteria

To determine whether OPOs modified UNOS' patient ranking criteria for kidneys, hearts or livers, we analyzed the responses to questions 32-33, 38-39, and 44-45, respectively. For each OPO that responded "unable to determine because the transplant center allocates organs," we discussed these OPO's allocation practices with UNOS. (See tables XI.1-XI.3.)

Table XI.1: Modifications to UNOS Criteria for Prioritizing Potential Kidney Recipients

Criteria modification	Question 33—response item ^a
Increases the weight given to those patients on the list the longest.	1
Except for six antigen matches, changes the weight given to HLA matching.	2 or 12 (other) <ul style="list-style-type: none"> Increases the weight given to HLA matching. Changes the matching criteria.
Changes the weight given to highly sensitized patients.	3, 4, or 11
Changes the weight given to pediatric patients.	7 or 8
Changes other factor(s).	9 or 12 (other) <ul style="list-style-type: none"> Weight is given to patients on experimental protocols.

^aFor purposes of our analysis, we did not consider response items 5 or 12 (other—"kidney/pancreas patients are given priority") to be modifications to UNOS' criteria because UNOS does not consider these modifications as changes to its criteria.

Table XI.2: Modifications to UNOS Criteria for Prioritizing Potential Heart Recipients

Criteria modification	Question 39—response item
Uses more than two medical urgency categories.	6
Increases the weight given to the distance from the donor.	4
Uses a point system instead of a priority system.	8 (other) <ul style="list-style-type: none"> Uses a point system instead of a priority system.
Changes other factor(s).	1, 5, 7, or 8 (other) <ul style="list-style-type: none"> The most ill patients within a category are transplanted first PRA is considered.

Table XI.3: Modifications to UNOS
Criteria for Prioritizing Potential Liver
Recipients

Criteria modification	Question 45—response item
Decreases the weight given to patients waiting the longest.	5 (other) • Decreases the weight given to patients waiting the longest.
The potential recipients' distance from donor is weighted.	3
Increases the weight given to medical urgency.	5 (other) • Increases the weight given to medical urgency.

Determining Criteria for Consideration of Patients in the OPO Service Area

To determine whether or not all patients in the OPO's service areas were considered as of December 31, 1991 for kidneys, hearts, and livers we analyzed the responses to questions 28, 35, and 41, respectively.¹ We determined that OPOs used an OPO-wide list, a transplant center list, or a subset list as described in tables XI.4-XI.6.

¹We determined that OPOs that only used one allocation policy for an organ in 1991 were using that policy as of December 31, 1991. For OPOs that reported they used more than one policy, we reviewed comments on their questionnaires and in some cases called the OPOs to determine (1) if the OPO used these policies for the entire year and (2) if not, which policy the OPO used for the latter part of 1991.

Table XI.4: GAO Criteria for Classifying OPOs' Kidney Allocation Systems

Types of kidney allocation systems	Question 28—response item
OPO-wide list: One or both kidneys are allocated using a single list that includes all potential recipients listed with the OPO.	1, 2, 5, or 7 (other) • One kidney is allocated using an OPO list and the other kidney is allocated using a list of patients in the South- Eastern Organ Procurement Foundation. ^a • First kidney is allocated using a single OPO list of all potential recipients and the second kidney is allocated using a transplant center's list.
Transplant Center List: One or both kidneys are allocated using a transplant center's list of recipients.	3, 5, 6, or 7 (other) • First kidney is allocated using a single OPO list of all potential recipients and the second kidney is allocated using a transplant center's list. • Both kidneys are first allocated using a transplant center's list of recipients. ^b
Subset of OPO List: One or both kidneys are allocated using a list of recipients from a group of transplant centers that are a subset of the OPO.	4 or 6

^aOPOs that are members of the South-Eastern Organ Procurement Foundation share kidneys with other members of the Foundation. This system was in place before UNOS was established.

^bWhile this response is similar to response item 3, some OPOs responded that only the first part of response item 3 applied. For example, after offering an organ to a single transplant center, an OPO-wide list was often used.

Table XI.5: GAO Criteria for Classifying OPOs' Heart Allocation Systems

Types of heart allocation systems	Question 35—response item
OPO-wide list: A heart is allocated using a single list that includes all potential recipients listed with the OPO.	1 or 2
Transplant Center List: A heart is allocated using a transplant center's list of recipients.	3 or 5 (other) • A heart is first allocated using a transplant center's list of recipients. ^a
Subset of OPO List: A heart is allocated using a list of recipients from a group of transplant centers that are a subset of the OPO.	4

^aWhile this response is similar to response item 3, some OPOs responded that only the first part of response item 3 applied. For example, after offering an organ to a single transplant center, an OPO-wide list was often used.

Table XI.6: GAO Criteria for Classifying OPOs' Liver Allocation Systems

Types of liver allocation systems	Question 41—response item
OPO-wide list: A liver is allocated using a single list that includes all potential recipients listed with the OPO.	1 or 2
Transplant Center List: A liver is allocated using a transplant center's list of recipients.	3 or 5 (other) • A liver is first allocated using a transplant center's list of recipients. ^a
Subset of OPO List: A liver is allocated using a list of recipients from a group of transplant centers that are a subset of the OPO.	4

^aWhile this response is similar to response item 3, some OPOs responded that only the first part of response item 3 applied. For example, after offering an organ to a single transplant center, an OPO-wide list was often used.

Major Contributors to This Report

Human Resources Division, Washington, D.C.

Janet L. Shikles, Director, Health Financing and Policy Issues,
(202) 512-7119
Rose Marie Martinez, Assistant Director
Roy B. Hogberg, Assignment Manager
Claude B. Hayeck, Evaluator
Susan L. Sullivan, Senior Social Science Analyst
Steve Machlin, Statistician

Office of the General Council

Craig H. Winslow, Senior Attorney

Los Angeles Regional Office

Ronald G. Viereck, Regional Assignment Manager
Tim Fairbanks, Evaluator-in-Charge
Susan Spitzer, Evaluator
Howard Cott, Evaluator
Edward Nash, Computer Analyst

Boston Regional Office

Robert D. Dee, Regional Management Representative
Betty Clark, Evaluator
Janet Boswell, Evaluator

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